Health Rights as a Limitation to Grant of Injunctions

for Pharmaceutical Patents in the EU

Johanna Rahnasto
Pro gradu -tutkielma
13.10.2018
Immateriaalioikeus ja EU -projekti
Oikeustieteellinen tiedekunta
Helsingin yliopisto

HELSINGIN YLIOPISTO
HELSINGFORS UNIVERSITET
UNIVERSITY OF HELSINKI

Tiedekunta/Osasto - Fakultet/Sektion – Faculty Faculty of Law		Laitos - Institution – Department
Tekijä - Författare – Author Johanna Rahnasto		
Työn nimi - Arbetets titel – Title Health Rights as a Limitation to Grant of Injunctions for Pharmaceutical Patents in the EU		
Oppiaine - Läroämne – Subject Intellectual Property Law		
Työn laji - Arbetets art – Level Master's Thesis	Aika - Datum – Month and year October 2018	Sivumäärä - Sidoantal – Number of pages XVII + 85

Tiivistelmä - Referat – Abstract

The research discusses whether health rights can be used as a discretionary limitation in the grant of permanent injunctions for pharmaceutical patents in the EU. The method is predominantly legal dogmatic with some comparative law as well as law and politics. The research contributes to the discussions of what the role of the right to exclude is, whether courts should have discretion in granting injunctions after infringement has been established and what the relationship of intellectual property and human rights is.

The traditional starting point of patent law is a strong right to exclude. This means that injunctions are issued as a matter of course when infringement has been established. In the case of pharmaceuticals the exercise of the right to exclude can sometimes result in a socially valuable product becoming unavailable to patients. It is therefore reasonable to ask whether the right to exclude should sometimes be overridden by public health concerns. Health rights refer to these public health concerns, including access to medicine and right to highest attainable level of health, as provided in various human rights instruments.

The EU Enforcement Directive provides that courts must have authority to grant injunctions. It also says that remedies must be effective, proportionate and dissuasive. To fulfil all these requirements any particular remedy should be selected based on the facts at hand. In the USA, the Supreme Court's *eBay* judgment made granting injunctions entirely discretionary. Courts have kept issuing injunctions for pharmaceutical patents in most cases, but consideration of public interest factors has become more routine. Injunctive relief might be denied if the injunction would make a medically important product unavailable to a substantial patient population, for example if the infringing product were not entirely substitutable with other products. Taking into account the human rights framework of the EU, it seems that EU courts would have the authority to take into account these kinds of facts and exercise similar discretion. Health rights could in individual cases weigh more than the patentee's right to exclude. Despite this, the current practices are unlikely to change without the emergence of a landmark case that might be referred to the Court of Justice of the EU.

As a conclusion, no legislative changes would be needed in the EU in order to adopt discretion in granting permanent injunctions. The lenient wording of the enforcement provisions, the principle of proportionality and the various human rights commitments of EU Member States provide sufficient legal grounds for exercising this kind of judicial discretion. In the light of the EU health rights framework the possibility to balance competing interest according to individual circumstances seems justified. Yet, the threshold for intervening with normal exercise of patent rights should be set quite high. In standard cases there would be no reason not to prioritize interests of the patentee. In the long run these interests also support public interests indirectly. Therefore the existence of discretion would not necessarily undermine exclusivity-based business models or incentives for pharmaceutical research and development.

Avainsanat – Nyckelord – Keywords
patent, enforcement, injunction, intellectual property, human rights, right to health, pharmaceuticals

Säilytyspaikka – Förvaringställe – Where deposited
Helsinki University Library

Muita tietoja – Övriga uppgifter – Additional information

Table of Contents

References

Legislation

International Treaties:

Agreement on the Trade Related Aspects of Intellectual Property (1994) (TRIPS)

Constitution of the World Health Organization (1946)

European Convention on Human Rights as amended by Protocols Nos. 11 and 14 (1950) (ECHR)

European Social Charter (1961)

International Covenant on Economic, Social and Cultural Rights (1966)

Paris Convention for the Protection of Industrial Property (1883)

Universal Declaration of Human Rights (1948)

European Union:

Agreement on Unitary Patent Court (2013/C 175/01) (UPCA)

Charter of Fundamental Rights of the European Union (2000/C 364/01) (CFR)

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions

Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights

Treaty on the Functioning of the European Union (2012/C 326/01) (TFEU)

United States of America:

Patent Act, 35 U.S.C. (Last amended in 2012)

Tariff Act, 19 U.S.C. Part II (Last amended in 2004)

Official sources

CESCR 2000	UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 11 August 2000, E/C.12/2000/4.
CESCR 2001	UN Committee on Economic, Social and Cultural Rights (CESCR) statement, Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights, 14 December 2001, E/C.12/2001/15.
CESCR 2006	UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 17: The Right of Everyone to Benefit from the

	Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c)), 12 January 2006, E/C.12/GC/17.
Doha Declaration	Doha Declaration On The TRIPS Agreement And Public Health. Adopted on 14 November 2001.
EXPH Opinion 2018	European Commission's Expert Panel on Effective Ways of Investing in Health: Opinion on Innovative payment models for high-cost innovative Medicines. 17.1.2018.
IHRB 2009	Institute for Human Rights and Business, Setting Boundaries: Clarifying the Scope and Content of the Corporate Responsibility to Respect Human Rights, December 2009.
Pharmaceutical Sector Inquiry 2009	European Commission, Pharmaceutical Sector Inquiry. Final Report. 8 July 2009.
Preparatory Committee 2014	Table with explanatory notes to the changes made by the Legal Group of the Preparatory Committee in the 17th draft of the Rules of Procedure. 31.10.2014. https://www.unified-patent-court.org/sites/default/files/Digest_Legal_Group_17th_Draft_RoP.PDF Accessed 20 July 2018.
ROP Digest 2014	Responses to the Public Consultation on the Rules of Procedure of the UPC – Digest of Comments Received. 16th Version. 6 March 2014. https://www.unified-patent-court.org/sites/default/files/rop-digest.pdf Accessed 20 July 2018.
Sub-Commission on Human Rights resolution 2000/7	Office of the High Commissioner for Human Rights: Intellectual property rights and human rights – Sub-Commission on Human Rights resolution 2000/7.
UN Guiding Principles 2011	United Nations Guiding Principles on Business and Human Rights Implementing the United Nations "Protect, Respect and Remedy" Framework 2011.
UN Report 2008	United Nations Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (A/63/263). General Assembly 11 August 2008. Includes as Annex the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines.
UN Report 2009	United Nations Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health, Paul Hunt (A/HRC/11/12/Add.2). General Assembly 18 May 2009. Includes as Addendum Mission to GlaxoSmithKline.
White Paper 2007	EU Commission's White Paper Together for Health: A Strategic Approach for the EU 2008-2013. COM(2007) 630 final. 23 October 2007.

Case law

Europe

Court of Justice of the European Union (CJEU):

C-275/06, *Productores de Música de España (Promusicae)* v. *Telefónica de España SAU*. 29 January 2008.

C-34/10 *Oliver Brüstle* v. *Greenpeace eV*. 18 October 2011.

C-70/10, *Scarlet Extended NV* v. *Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM)*. 24 November 2011.

C-457/10 P *AstraZeneca AB, AstraZeneca plc* v. European Commission. 6 December 2012.

C-170/13 *Huawei Technologies Co. Ltd*. v. *ZTE Corp*. 16 July 2015.

C‑201/13 *Johan Deckmyn, Vrijheidsfonds VZW* v.*Helena Vandersteen, Christiane Vandersteen, Liliana Vandersteen, Isabelle Vandersteen, Rita Dupont, Amoras II CVOH, WPG Uitgevers België*. 3 September 2014.

European Court of Human Rights: (alphabetical order)

Balan v. *Moldova*, No. 19247/03. 29 January 2008.

James and Others v. *United Kingdom*, No. 8793/79. 21 February 1986.

Lopes De Sousa Fernandes v. *Portugal*, No. 56080/13. 19 December 2017.

Smith Kline and French Laboratories Ltd v. *the Netherlands*, No. 12633/87. 4 October 1990.

Finland:

KKO:2003:127, N:o 3114, diary S2001/489. 18 December 2003.

Germany:

Bundesgerichtshof: *Polyferon*. X ZR 26/92. 5 December 1995.

Bundesgerichtshof: *Raltegravir*. X ZB 2/17. 11 July 2017.

United Kingdom:

Supreme Court of the United Kingdom: *Coventry and others* v. *Lawrence and another* (No 2) [2014] UKSC 46. 23 July 2014.

United Kingdom High Court of Justice: *HTC Corporation* v. *Nokia Corporation* [2013] EWHC 3778 (Pat). 3 December 2013.

United States of America

Supreme Court of the United States:

eBay Inc. et al. v. *MercExchange L.L.C.*, 547 U.S. 388 (2006) and the concurring opinion of Kennedy, J.

United States Court of Appeals:

Panduit Corp. v. *Stahlin Bros. Fibre Works*, Inc., 575 F.2d 1152 (6th Cir. 1978).

W.l. Gore & Associates, Inc. v. *Garlock, Inc.* 842 F.2d 1275 (Fed. Cir. 1988).

Edwards Lifesciences AG and *Edwards Lifesciences LLC* v. *CoreValve, Inc.* and *Medtronic CoreValve, LLC* 699 F.3d 1305 (Fed. Cir. 2012).

Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc. v. *Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC* 872 F.3d 1367 (Fed. Cir. 2017).

District Courts:

Johnson & Johnson Vision Care v. *Cibe Vision Corp.* 712 F.Supp.2d 1285 (M.D. Florida 2010).

International Trade Commission:

Investigation No. 337-TA-543. Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets. October 2011.

Others

Delhi High Court: *Bayer Intellectual Property GmbH* v. *Ajanta Pharma Ltd*. 4 January 2017.

Literature

Aarnio 1997	Aarnio, Aulis, Oikeussäännösten systematisointi ja tulkinta in Häyhä, Juha (ed.), Minun metodini. Werner Söderström Lakitieto Oy 1997.
Ahmadiani & Nikfar 2016	Ahmadiani, Saeed – Nikfar, Shekoufeh, Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective. DARU Journal of Pharmaceutical Sciences 24(13) 2016, p. 1–7.
Airaksinen – Pulkkinen – Rasinaho 2018a	Airaksinen, Manne – Pulkkinen, Pekka – Rasinaho, Vesa, Osakeyhtiölaki I. Alma Talent 2018.
Airaksinen – Pulkkinen – Rasinaho 2018b	Airaksinen, Manne – Pulkkinen, Pekka – Rasinaho, Vesa, Osakeyhtiölaki II. Alma Talent 2018.
Allen 2013	Allen, Scott A., "Justifying" the Public Interest in Patent Litigation. Indiana Law Review 88 2013, p. 1047–1088.
Ayres & Klemperer 1999	Ayres, Ian – Klemperer, Paul, Limiting Patentee's Market Power without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies. Michigan Law Review 97 1999, p. 985–1033.
Barnes 2018	Barnes, Arianna Jane, Abuse of dominance causing congestion in the pharmaceutical industry: what is the cure in light of the Reckitt Benckiser (Case CE/8931/08) decision? European Competition Law Review 39(2) 2018, p. 49–63.
Bennet – Roux-Vaillard – Mammen 2015	Bennet, Stephen – Roux-Vaillard, Stanislas – Mammen, Christian, Shifting attitudes to injunctions in patent cases. Managing Intellectual Property 246 2015, p. 22–26.
Beran 2016	Beran. Roy G., Generic Substitution When Similar May Not Mean the Same. Medicine and Law 35 2016, p. 76–86.
Bharadwaj 2018	Bharadwaj, Ashish, Patent injunction and the public interest in India. European Intellectual Property Review 40(1) 2018, p. 55–58.
Boscheck 2015	Boscheck, Ralf, Intellectual Property Rights and the Evergreening of Pharmaceuticals. Intereconomics 50(4) 2015, p. 221-226.
Broes et al. 2016	Broes, Stefanie – Schumacher, Sarah – Preuveneers, Geert – Huys, Isabelle, Intellectual property rights and regulatory exclusivities in the pharmaceutical sector: challenges and future improvements. Intellectual Property Quarterly 1 2016, p. 19–43.
Brown 2016	Brown, James Robert, Patents and Progress. Perspectives on Science 25(5) 2016, p. 505–528.
Carbone 2003	Carbone, June, Ethics, Patents and the Sustainability of the Biotech Business Model. International Review of Law, Computers & Technology 17(2) 2003, p. 203–218.
Christoffersen 2015	Christoffersen, Jonas, Human rights and balancing: The principle of proportionality in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.

Civan 2008	Civan, Abdulkadir, Intellectual Property Rights of Pharmaceutical Companies and Access to Medicines. Journal of Academic Studies 38 2008, p. 1–16.
Cornwell 2018	Cornwell, Jane, Injunctions and monetary remedies compared: the English judicial response to the IP Enforcement Directive. European Intellectual Property Review 40(8) 2018, p. 490–500.
Crompton 2010	Crompton, Simon, Why international forum shopping will increase. Interview with Iain Campbell. Managing Intellectual Property 202 2010, p. 47.
den Exter 2010	den Exter, Andre, The Pharmaceutical Sector Inquiry: Hamlet in a Nutshell. European Journal of Health Law 17(2) 2010, p. 125-138.
Derclaye 2009	Derclaye, Estelle, Should patent law help cool the planet? An inquiry from the point of view of environmental law: Part 2. European Intellectual Property Review 31(5) 2009, p. 227-235.
Diessel 2007	Diessel, Benjamin H., Trolling for Trolls: The Pitfalls of the Emerging Market Competition Requirement for Permanent Injunctions in Patent Cases Post-*eBay*. Michigan Law Review 106 2007, p. 305–346.
Dreyfuss 2015	Dreyfuss, Rochelle C., An International Perspective I: A View from the United States in Pila, Justine – Wadlow, Christopher, The Unitary EU Patent System. Hart Publishing 2015.
Ducoulombier 2015	Ducoulombier, Peggy, Interaction between human rights: Are all human rights equal? in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Elmahjub 2016	Elmahjub, Ezieddin, A case for flexible intellectual property protection in developing countries: brief lessons from history, psychology and economics. European Intellectual Property Review 38(1) 2016, p. 31–42.
Enerson 2004	Enerson, Benjamin D., Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine. Cornell Law Review 89(685) 2004, p. 686–720.
European Copyright Society 2015	European Copyright Society, Limitations and exceptions as key elements of the legal framework for copyright in the European Union - opinion on the judgment of the CJEU in Case C-201/13 Deckmyn. European Intellectual Property Review 37(3) 2015, p. 129–133.
Feldman & Price 2014	Feldman, Robin – Price II, W. Nicholson, Patent Trolling: Why Bio & Pharmaceuticals Are at Risk. Stanford Technology Law Review 17 2014 p. 773-808.
Fox 2018	Fox, Nicholas, Brevets sans frontieres: how much litigation will actually take place in the Unified Patent Court? European Intellectual Property Review 40(2) 2018, p. 85–94.
Geiger & Izyumenko 2018	Geiger, Christophe – Izyumenko, Elena, Intellectual Property before the European Court of Human Rights. Center for International Intellectual Property Studies (CEIPI) Research Paper No. 2018-01.

Gervais 2015	Gervais, Daniel, Human rights and the philosophical foundations of intellectual property in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Golden 2010	Golden, John M., Principles for Patent Remedies. Texas Law Review 88 2010, p. 505–592.
Golden 2014	Golden, John M., Litigation in the Middle: The Context of Patent-Infringement Injunctions. Texas Law Review 92 2014, p. 2075–2115.
Grosse Ruse-Khan 2015	Grosse Ruse-Khan, Henning, Overlaps and conflict norms in human rights law: Approaches of European courts to address intersections with intellectual property rights in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Helfer & Austin 2011	Helfer, Laurence R. – Austin, Graeme W., Human Rights and Intellectual Property – Mapping the Global Interface. Cambridge University Press 2011.
Helfer 2015	Helfer, Laurence R., Mapping the interface between human rights and intellectual property in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Helm 2009	Helm, Katherine A., The battle over global drug markets: enforcement of pharmaceutical patents in the United States, Europe and Japan. Journal of Intellectual Property Law & Practice 4(1) 2009, p. 39–50.
Helm 2006	Helm, Jeremiah S., Why Pharmaceutical Firms Support Patent Trolls: The Disparate Impact of Ebay v. Mercexchange on Innovation. Michigan Telecommunications and Technology Law Review 13(1) 2006, p. 331–343.
Hervey & McHale 2015	Hervey, Tamara K. – McHale, Jean V., European Union Health Law – Themes and Implications. Cambridge University Press 2015.
Hestermeyer 2007	Hestermeyer, Holger, Human Rights and the WTO: The Case of Patents and Access to Medicines. Oxford University Press 2007.
Hurri 2004	Hurri, Samuli, Supernormit ja sisältö. Lakimies 1 2004, p. 109–125.
Husa 2009	Husa, Jaakko, Konstitutionalismin mahdottomuus? Lakimies 7–8 2009, p. 1141–1153.
Jacobs & Zhang 2013	Jacobs, Michael – Zhang, Patrick, A return to traditional injunctive relief for patent owners? Managing Intellectual Property 234 2013, p. 34–37.
Jelf 2017	Jelf, Myles, Discretion in Post-Trial Injunctive Relief before the UPC? (presentation) EPLAW – Congress and Assembly 2017 Documents http://eplaw.org/wp-content/uploads/2017/11/EPLAW-Discretion-Injunctive-Relief-UPC.pdf.
Johnson 2015	Johnson, Alan, Looking Forward: A User Perspective in Pila, Justine – Wadlow, Christopher (ed.), The Unitary EU Patent System. Hart Publishing 2015.
Jyränki 1997	Jyränki, Antero, Toiset työt, toiset metodit in Häyhä, Juha (ed.), Minun metodini. Werner Söderström Lakitieto Oy 1997.
Karhu 2003	Karhu, Juha, Perusoikeudet ja oikeuslähdeoppi. Lakimies 5 2003, p. 789–807.

Kathuria & Lai 2018	Kathuria, Vikas – Lai, Jessica C., Royalty rates and non-disclosure agreements in SEP licensing: implications for competition law. European Intellectual Property Review 40(6) 2018, p. 357–367.
Klar 2006	Klar, Richard B., Ebay Inc. v. Mercexchange, L.L.C.: The Right to Exclude under U.S. Patent Law and the Public Interest. Journal of the Patent and Trademark Office Society 88 2006, p. 852–858.
Kuhlik 2004	Kuhlik, Bruce N., The Assault on Pharmaceutical Intellectual Property. The University of Chigaco Law Review 71 2004, p. 93–109.
Lee & Hunt 2012	Lee, Joo-Young – Hunt, Paul, Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines. Journal of Law, Medicine and Ethics 40(2) 2012, p. 220–233.
Lee & Melamed 2016	Lee, William F. – Melamed, Douglas, Breaking the Vicious Cycle of Patent Damages. Cornell Law Review 101 2016, p. 385–466.
Malani & Masur 2013	Malani, Anup – Masur, Jonathan S., Raising the Stakes in Patent Cases. The Georgetown Law Journal 101 2013, p. 637–687.
Mansnerus 2016	Mansnerus, Juli, Commercialisation of Advanced Therapies – A Study of the EU Regulation on Advanced Therapy Medical Products. Unigrafia 2016.
Marfe et al. 2015	Marfe, Mark – Reetz, Alexander – Pecnard, Camille – Fruscalzo, Riccardo – van der Velden, Ruud, The power of national courts and the Unified Patent Court to grant injunctions: a comparative study. Journal of Intellectual Property Law & Practice 10(3) 2015, p. 180–190.
Marks 2016	Marks, Stephen P., Normative Expansion of the Right to Health and the Proliferation of Human Rights. George Washington International Law Review 49 2016, p. 101–144.
Matthews 2011	Matthews, Duncan, Intellectual Property, Human Rights and Development – The Role of NGOs and Social Movements. Edward Elgar Publishing 2011.
Matthews 2015	Matthews, Duncan, Right to health and patents in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Matthews & Gurgula 2016	Matthews, Duncan – Gurgula, Olga, Patent strategies and competition law in the pharmaceutical sector: implications for access to medicines. European Intellectual Property Review 38(11) 2016, p. 661–667.
McDermott 2012	McDermott, Eileen, How to Survive the Patent Cliff. Managing Intellectual Property 216 2012, p. 22-25.
Merges 2011	Merges, Robert P., Justifying Intellectual Property. Harvard University Press 2011.
Merges & Duffy 2011	Merges, Robert Patrick – Duffy, John Fitzgerald, Patent Law and Policy: Cases and Materials. 5th Edition. LexisNexis/Matthew Bender & Company 2011.
Minn 2018a	Minn, Mari, Patenting practices in the competitive European pharmaceutical market: a thin line between patents, innovation and strategy. European Intellectual Property Review 40(1) 2018, p. 16-20.

Minn 2018b	Minn, Mari, Patent settlement agreements and the refusal to license in the light of competition law. European Intellectual Property Review 40(2) 2018, p. 109–112.
Morgan 1996	Morgan, Derek, Health Rights, Ethics and Justice: The Opportunity Costs of Rhetoric in McLean, Sheila A M. (ed.), Contemporary Issues in Law, Medicine and Ethics. Dartmouth Publishing Company Limited 1996.
Mylly 2009	Mylly, Tuomas, Intellectual Property and European Economic Constitutional Law. Publications of IPR University Center 4. Gummerus Kirjapaino Oy 2009.
Mylly 2015	Mylly, Tuomas, The constitutionalization of the European legal order: Impact of human rights on intellectual property in the EU in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Ng 2009	Ng, Elizabeth Siew-Kuan, Balancing Patents and Access to Medicine. Singapore Academy of Law Journal 21 2009, p. 457–484.
Neuvonen & Rautiainen 2015	Neuvonen, Riku – Rautiainen, Pauli, Perusoikeuksien tunnistaminen ja niiden sisällön määritteleminen Suomen perusoikeusjärjestelmässä. Lakimies 1 2015, p. 28–53.
Nicolic 2017	Nicolic, Igor, Who needs injunctions? Alternative remedies in standard essential patents disputes. Journal of Intellectual Property Law & Practice 12(2) 2017, p. 126–135.
Nieminen 2010	Nieminen, Liisa, Eurooppalainen konstitutionalismi. Lakimies 5 2010, p. 773–790.
Norrgård 2002	Norrgård, Marcus, Intermistiska förbud i immatrerialrätten. Kauppakaari 2002.
Norrgård 2004	Norrgård, Marcus, Väliaikaiset kiellot patenttioikeudessa. Defensor Legis 6 2004, p. 1063–1079.
Norrgård 2005	Norrgård, Marcus, The role conferred on the national judge by directive 2004/48/EC on the enforcement of intellectual property rights. ERA Forum 6(4) 2005, p. 503–514.
Norrgård 2010	Norrgård, Marcus, The European Principles of IP Enforcement: Harmonisation Through Communication? (20 p.) in Ohly, Ansgar (ed.), Common Principles of European Intellectual Property Law. Mohr Siebeck 2010.
Norrgård & Bruun 2007	Norrgård, Marcus – Bruun, Niklas, Analogiamenetelmäpatentin suojapiiri. Osa 1. Lakimies 5 2007, p. 679–705.
Nyblin 2009	Nyblin, Klaus, Mihin suuntaan lääkekorvausjärjestelmä kehittyy? Defensor Legis 6 2009, p. 915–946.
Oesch 2017	Oesch, Rainer, Johdatus aiheeseen: yleinen etu ja immateriaalioikeuden suoja – mitä uutta? in Oesch, Rainer – Eloranta, Mikko – Heino, Mari – Kokko, Mira (ed.), Immateriaalioikeudet ja yleinen etu. Alma Talent 2017.
Ojanen 2009	Ojanen, Tuomas, Perus- ja ihmisoikeudet – eurooppalaisen konstitutionalismin Akilleen kantapää? Lakimies 7–8 2009, p. 1106–1124.

Ojanen 2014	Ojanen, Tuomas, Valtiosääntöoikeus kansainvälistymisen kohteena ja välittäjänä. Lakimies 7–8 2014, p. 937–952.
Oker-Blom 2009	Oker-Blom, Max, Oikeustaloustieteen eli taloudellisten argumenttien merkityksestä Raimo Siltalan oikeuslähdeopissa in Kolehmainen, Esa (ed.), Oikeus ja kritiikki I – Raimo Siltalan oikeustieteen tieteenteoria. Forum Iuris 2009.
Oker-Blom 2013	Oker-Blom, Max, »Incentive vs access» – lyhyt katsaus immateriaalioikeuden ikuisuuskysymykseen. Lakimies 7–8 2013, p. 1356–1363.
Otto & Wolters 2017	Otto, Kerstin – Wolters, Anna, Federal Patent Court grants compulsory license. Bird & Bird 24 July 2017.
Owoeye & Owoeye 2018	Owoeye, Olasupo – Owoeye, Oluwabusayo, Intellectual property, access to medicines and universal health coverage through a health rights lens. European Intellectual Property Review 40(1) 2018, p. 49–54.
Papadupoulou 2018	Papadupoulou, Frantzeska, The impact of regulatory systems in life sciences: emerging exclusive rights growing outside the scope of the traditional intellectual property system? European Intellectual Property Review 40(5) 2018, p. 301–310.
Peukert 2015	Peukert, Alexander, The fundamental right to (intellectual) property and the discretion of the legislature in in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Picht 2016	Picht, Peter, The ECJ rules on standard-essential patents: thought and issues post-Huawei. European Competition Law Review 37(9) 2016, p. 365–375.
Pila 2015	Pila, Justine, An Historical Perspective I: The Unitary Patent Package in Pila, Justine – Wadlow, Christopher (ed.), The Unitary EU Patent System. Hart Publishing 2015.
Posner 2012	Posner, Richard A., Why there are too many patents in America. The Atlantic 12 July 2012.
Rachlin 2014	Rachlin, Mark, Developments in Injunctive Relief in Health Care Patent Cases. Intellectual Property Litigation 26(1) 2014.
Rahnasto 2003	Rahnasto, Ilkka, Intellectual Property Rights, External Effects and Anti-trust Law: Leveraging IPRs in the Communications Industry. Oxford University Press 2003.
Raitio 2013	Raitio, Juha, Eurooppaoikeus ja sisämarkkinat. 3rd Edition. Alma Talent Oy 2013.
Rautiainen 2011	Rautiainen, Pauli, Moninaisuudessaan yhtenäinen Eurooppa: konsensusperiaate ja valtion harkintamarginaalioppi. Lakimies 6 2011, p. 1152–1171.
Riley & Allen 2015	Riley, P. Andrew – Allen, Scott A., The Public Interest Inquiry for Permanent Injunctions or Exclusion Orders: Shedding the Myopic Lens. Vanderbilt Journal of Entertainment & Technology Law 17(3) 2015, p. 751–779.
Russell & Churi 2016	Russell, Kelly – Churi, Asawari, Litigation strategies in the UPC. Intellectual Property Magazine 4 2016.
Schulten 2004	Schulten, Gerhard af, Osakeyhtiölain kommentaari II. Talentum 2004.

Seaman 2016	Seaman, Christopher B., Permanent Injunctions in Patent Litigation After eBay: An Empirical Study. Iowa Law Review 101 2016, p. 1949–2019.
Sellin 2015	Sellin, Jennifer Anna, Does One Size Fit All? Patents, the Right to Health and Access to Medicines. Netherlands International Law Review 62 2015, p. 445–473.
Seville 2013	Seville, Catherine, Rhetoric and Reality in Pila, Justine – Ohly, Angsar (ed.), The Europeanization of Intellectual Property Law: Towards a European Legal Methodology. Oxford University Press 2013.
Shadlen et al. 2011	Shadlen, Kenneth C. – Guennif, Samira – Guzman, Alenka – Lalitha, N., Globalization, intellectual property rights, and pharmaceuticals: meeting the challenges to addressing health gaps in the new international environment in Shadlen, Kenneth C. – Guennif, Samira – Guzman, Alenka – Lalitha, N. (ed.), Intellectual Property, Pharmaceuticals and Public Health – Access to Drugs in Developing Countries. Edward Elgar Publishing 2011.
Sichelman 2014	Sichelman, Ted, Purging Patent Law of "Private Law" Remedies. Texas Law Review 92 2014, p. 517–571.
Slowinski 2018	Slowinski, Peter R., Germany: comment on the German Federal Supreme Court judgment "Raltegravir". International Review of Intellectual Property and Competition Law 49(1) 2018, p. 125–130.
Smith 2015	Smith, Rhona, Interaction between international human rights law and the European legal framework in Geiger, Christophe (ed.), Research Handbook on Human Rights and Intellectual Property. Edward Elgar Publishing 2015.
Smits & Bull 2013	Smits, Jan – Bull, William, The Europeanization of Patent Law: Towards a Competitive Model in Ohly, Angsar – Pila, Justine (ed.), The Europeanization of Intellectual Property Law. Oxford University Press 2013.
Song & Han 2016	Song, Chie Hoon – Han, Jeung-Whan, Patent Cliff and Strategic Switch: Exploring Strategic Design Possibilities in the Pharmaceutical Industry. SpringerPlus 5(692) 2016, p. 1–14.
Stiefel & Carter 2016	Stiefel, Aaron – Carter, Krista, 10 Years Later – Impact of eBay on Patent Injunctions in the Life Sciences. Bloomberg BNA: Medical Devices Law & Industry Report 21 June 2016, p. 1–5.
Syrjänen 2009	Syrjänen, Jussi, Arvioita Siltalan oikeuslähdeopista in Kolehmainen, Esa (ed.), Oikeus ja kritiikki I – Raimo Siltalan oikeustieteen tieteenteoria. Forum Iuris 2009.
Torti 2012	Torti, Valerio, IPRs, competition and standard setting: in search of a model to address hold-up. European Competition Law Review 33(9) 2012, p. 387–397.
Trogan 2005	Trogan, Eugene, Balancing the Need for Innovative Drugs While Providing Lower Cost Alternatives to Consumers: Hatch-Waxman Reviewed. Medicine and Law 24 2005, p. 355–368.
Tuominen 2012	Tuominen, Nicoleta, An IP perspective on defensive patenting strategies of the EU pharmaceutical industry. European Intellectual Property Review 34(8) 2012, p. 541–551.

Tuori 2018	Tuori, Kaarlo, Crises and European Constitutionalism. Tidskrift utgiven av Juridiska Föreningen i Finland 1 2018, p. 47–50.
von Falck	von Falck, Andreas, Compulsory licenses as a defense in pharmaceutical and biotech patent litigation. Pharmaceutical Patent Analyst 5(6) 2016, p. 351–353.
Walkila 2011	Walkila, Sonya, Euroopan unionin perusoikeuskirja EU-tuomioistuimen oikeuskäytännössä. Defensor Legis 6 2011, p. 813–820.
Walkila 2015a	Walkila, Sonya, Horizontal Effect of Fundamental Rights in EU Law. Tidskrift utgiven av Juridiska Föreningen i Finland 2 2015, p. 181–186.
Walkila 2015b	Walkila, Sonya, Perusoikeuksien turvaaminen Euroopan unionissa – tasapainoilua tavoitteiden ja keinojen ristiaallokossa. Defensor Legis 4 2015, p. 791–807.
Watanabe & Shi 2011	Watanabe, Mariko – Shi, Luwen, Sufficient but expensive drugs: a double-track system that facilitated supply capability in China in Shadlen, Kenneth C. – Guennif, Samira – Guzman, Alenka – Lalitha, N. (ed.), Intellectual Property, Pharmaceuticals and Public Health – Access to Drugs in Developing Countries. Edward Elgar Publishing 2011.
Whiting & Lorenzo 2016	Whiting, Laura – Lorenzo, Inmaculada, UPC scenario 5: Enforcing a patent inside and outside the UPC. Managing Intellectual Property 260 2016, p. 25–29.

Other sources

WHO (World Health Organization): Essential medicines and health products (http://www.who.int/medicines/areas/human_rights/en/) Accessed 18 June 2018.

EFPIA (European Federation of Pharmaceutical Industries and Associations) website (https://www.efpia.eu/) Accessed 11 July 2018.

EMA (European Medicines Agency): Adaptive pathways (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp) Accessed 19 July 2018.

Abbreviations

CESCR	Committee on Economic, Social and Cultural Rights
CJEU	Court of Justice of the European Union
eBay	US Supreme Court case *eBay* v. *MercExchange* (2006)
EMA	European Medicines Agency
ICESCR	International Covenant of Economic, Social and Cultural Rights
IP	Intellectual property
IPR	Intellectual property right
ITC	US International Trade Commission
R&D	Research and development
ROP	UPC Rules of Procedure
SEP	Standard essential patent
SPC	Supplementary protection certificate
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property
UPC	Unified Patent Court
UPCA	Agreement on a Unified Patent Court
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction

1.1 Background

Patents are an important reward and motivation for innovative pharmaceutical companies. Despite being only one of the many incentives provided for pharmaceutical companies,[1] they have maintained their position as valuable and cherished assets. The companies regularly use the right to exclude conferred by a patent to maintain an exclusive market for their products. Injunctions are sought for infringements that cannot be settled. The grant of an injunction after an established patent infringement remains quite automatic in the EU. Also in the US the grant of injunctions for pharmaceutical patents is the main rule even after the *eBay* judgment[2] changed the game for many other patents.

Recently human rights considerations have increased both generally and within intellectual property law. The realization of health rights has gained more attention also in developed countries, where pharmaceuticals are generally well available but not always accessible for everyone. Sometimes the use of injunctions can make a pharmaceutical unavailable or inaccessible to a part of the patient population. In these cases, it is relevant to ask whether the patent owner's right to exclude always prevails over public interest and the patients' right to health. From this setting arises the question whether health rights should be taken into account in the enforcement of pharmaceutical patents and how this could be done.

There are several ways in which the use of patents can be limited. The most popular in the EU has been competition law, which has been used to sanction practices contrary to the competition values of the EU. Another measure to control the behavior of pharmaceutical companies would be controlling the availability of injunctions. An injunction might be denied if it would compromise health rights to an unacceptable degree.

The discussion about whether injunctions should be discretionary or automatic[3] is very topical in patent law, and current trends seem to emphasize the need for balancing different interests.

---

[1] The others include regulatory data and market exclusivities and pricing and reimbursement mechanisms.
[2] 547 U.S. 388 *eBay* v. *MercExchange* (2006).
[3] Automatic injunctions mean that they are granted in all cases when a valid right has been infringed without the need for the patentee to argue why injunction is needed or necessary. In such a system, the court will not discuss or balance any competing interests, but the injunction is issued as a matter of course.

Pharmaceutical patents have always been subject to criticism and their effects on the realization of human rights and social justice have been widely discussed. Still, discretion in the grant of injunctions in the context of pharmaceutical patents remains a rather new idea. It might be argued that there are other mechanisms to take care of the realization of human rights and that courts dealing with patent matters should not be exposed to such considerations. Yet, most mechanisms only apply within a narrow time frame or a specific administrative phase, so the existence of an additional layer of control should not be downright rejected. The following analysis will conclude that discretion could indeed be exercised under European patent law without any legislative changes. However, there are reasons why the denial of injunctions should be limited to special circumstances and interests of the patentee should remain a central concern even if balancing with health rights is exercised.

1.2 Research Question and Limitations

My main research question in this thesis is as follows:

> Can health rights be used as a discretionary limitation in the grant of permanent injunctions for pharmaceutical patents in the EU?

The question can be broken down into sub-questions, including: Are injunctions always available as automatic remedies? Do EU courts have authority not to grant injunctions based on public interest? Do EU courts have discretion to take into account health rights in patent trials? Are there situations when it might be reasonable to deny a pharmaceutical patent injunctive relief? As follow-up questions I will discuss how this kind of discretion could be exercised and whether EU courts should use more discretion in granting injunctions for pharmaceutical patents.

As the research question implies, only permanent injunctions will be considered.[4] Preliminary injunctions are ruled out, so the word injunction will always refer to a permanent injunction unless otherwise specified. I also limit the analysis to pharmaceutical patents. The regulatory and business environment of medical devices is significantly different from that of

[4] The central legal dogmatic questions relating to preliminary injunctions include the prerequisites of grant, procedural questions as well as legal effects and suspension of the injunction. Especially the procedural aspects stand out in these discussions and they are very different from the issues relating to permanent injunctions. Norrgård 2002 p. 9.

pharmaceuticals,[5] so they are left out of the main analysis, although some examples are provided. Some statements also apply to medical devices.

The analysis is limited to developed countries. The main question concerns Europe, but perspectives from the USA will be carried along comparatively. In practice this limitation means that when discussing the right to health and access to medicine, the main issue is usually not about essential medicines not being available. Rather the issue is novel medicines not being affordable. The access problems of developing counties would be significantly different from those of the EU, and they are only touched upon lightly. USA is discussed thoroughly because of the extensive discussion around the topic there, their fundamentally different approach to injunctions and the fact that many major pharmaceutical companies are based there.[6]

Other means that could strengthen the realization of health rights in relation to patented inventions will not be extensively discussed. Minor comments are still made about them, these including the use of competition law, compulsory licensing and legislative action. The main analysis will only concern discretion in the grant of injunctions.

The research question connects tightly to the more general debates of the IP field. These include the relationship of IP and human rights as well as the relationship of property and liability rules. This analysis also contributes to the discussion of how absolute the patentee's right to exclude is and whether courts should exercise discretion in awarding injunctions after successful infringement suits. The discussions around these themes will be applied to the specific case of pharmaceuticals and health rights.

1.3 Methods and Materials

The method of this thesis is predominantly legal dogmatic, most of all practical legal dogmatic. This means that I will interpret the legal state of patent injunctions and health rights from the perspective of current society. The method is argumentative and leans on a variety of legal sources. Essentially, it will be an exercise of weighing and balancing the opposite interests surrounding the topics at hand.[7] Comparative law will also be utilized when discussing the

[5] Medical devices typically utilize multiple patents whereas pharmaceuticals usually only use one or a few. Medical devices are also not subject to a similar, strict authorization procedure, to name a few differences. Similar health rights arguments can be stated in both cases.
[6] Helm 2009 p. 39.
[7] On legal dogmatic methods see Aarnio 1997 p. 35–53.

applicability of US reasoning to a European setting, but it is not the main method. Additionally, because my research question centrally concerns a tension between two fundamental rights, part of the analysis is inevitably going to be influenced by values. Giving priority to one right over another or balancing competing interests is not a legal dogmatic exercise but a value-based conclusion. This is why I also employ law and politics in addition to the legal dogmatic approach. The starting point of the analysis will be current legal practice, so that the conclusions would have maximal practical significance.[8]

My research question brings together health rights, IP and pharmaceutical business. This combination can be seen in the set of references: the materials can be roughly classified into categories of human rights sources, intellectual property sources and pharmaceutical industry sources.[9] The analysis will start by discussion of international agreements and EU primary law concerning human rights and intellectual property. These instruments will be assigned substantial legal value. Some official documents (especially of the UN sphere) and case law will also be used. Apart from those, the majority of references will be European and US literature, especially research articles.[10]

As already mentioned, the research question implies a value-based assessment and is as such also emotionally triggering. Many scholars addressing the patenting practices of the pharmaceutical industry are clearly either on the "patent side" or "human rights side" of the debate.[11] In this thesis, I strive for neutrality and to give both interests the weight that belongs to them according to the legal dogmatic analysis. One goal of this thesis is to match the interests of patentees and the general public on this specific question in a way that would make taking sides unnecessary.[12]

---

[8] On methods of constitutional law see Jyränki 1997 p. 75–77.

[9] Of course, many references also combine more than one category.

[10] The role of international agreement and EU legislation in the traditional hierarchy of sources of law has been much discussed. In this thesis, I assume them as the primary starting point. In practice this means that human rights sources are highly esteemed. Secondary legislation, case law and literature are used to bring the perspectives of primary law to a sufficient level of detail and practical applicability. For more discussion, see Karhu 2003, Hurri 2004, Syrjänen 2009.

[11] This might also be an effect of framing, in this case rhetorically presenting the issue at hand to be either purely a human rights matter or a business matter. See Matthews 2011 p. 8–9. However, others are clearly opposing any kind of patent protection for medical applications. See e.g. Brown 2016.

[12] There will of course remain value-based choices, but what I would like to show is that the issue is not about whether one is pro or contra patents per se.

1.4 Structure

In chapter 2, I will introduce the position of the patentee's right to exclude as a fundamental right. As background, basics of property protection of IP will be provided. The chapter is concluded by an introduction to the innovative pharmaceutical business and its specific interests related to patents and exclusivity. Chapter 3 will introduce the content and legislative background of health rights. It will also address the question how these rights relate to IP and whether there is an inherent conflict between these bodies of law and how such conflict could be resolved. Human rights law based arguments to raise health rights over patent rights will be considered.

Chapter 4 will consider the specific situation of issuing injunctions. It will introduce the dilemma of whether injunctions should be automatic or discretionary and describe the current European and US practices. Drawing from the US *eBay* judgment, the possibilities of similar developments in the EU will be contemplated considering especially the Enforcement Directive and the Unified Patent Court. This chapter will conclude that it would indeed be possible to use health rights as a discretionary limitation to pharmaceutical patent enforcement in the EU and to bring human rights considerations into patent law.

Chapter 5 will take the conclusions of chapter 4 and answer more specifically the question how and when such discretion could be exercised within the current legal framework. The goal of this chapter is to find a just balance between the different interests and to formulate grounds on which an injunction might be denied. I will discuss corporate human rights compliance and the use of a public interest criterion, taking into account the patentee's possibilities to affect the outcome. Finally, the values behind the different options will be discussed. Chapter 6 concludes the finding of this study.

2. Right to Exclude and Pharmaceutical Business

2.1 Patents as Property Rights

2.1.1 Justification of Intellectual Property and Patents

The justification of intellectual property (IP; including patents) stems nowadays mostly from utilitarian ideas.[13] There are many rationales around which the justification of IP can be framed. Under natural law, IPRs result from the natural right of a person to the fruits of their work. This idea does not entirely suit patent law, but it can be detected in the human rights protection of IP as an indistinguishable form of property.[14] In addition, patents can be framed as a contract between the inventor and the society: limited exclusivity in exchange for disclosure of the invention. They can also be seen as rewards for contributing to the development of society or as incentives to create and innovate.[15] Lastly, patents can be conceptualized as prospects that provide the inventor security to develop the invention further, to prepare to enter the market and to search funding.[16]

The relevance of IP has increased in the recent decades as its scope and forms have expanded. The expansion of IP legislation has been criticized a lot and many have called for broader exceptions and limitations. Yet, IP already is subject to various limitations, starting from the careful definitions of protected subject-matter and limited terms of protection.[17] Simply the fact that the use of IP triggers criticism does not mean that the IP itself or its use would not be justified. The ultimate goal is a balance between the interests of the patentee and the public.

The traditional view is that limitations to exclusive rights should be interpreted narrowly.[18] As a result of this thinking, IPRs have often been prioritized over the interests protected by the

[13] Hestermeyer 2007 p. 29.
[14] *Id.* p. 30. The idea has its roots in Locke's philosophy, but contradicts current patent laws that require a registration procedure and limit patent rights temporally. It is more applicable to copyright, where the protection lasts over the creator's lifetime and also includes moral rights.
[15] Malani & Masur 2013 p. 642–643.
[16] Hestermeyer 2007 p. 30–33.
[17] Oesch 2017 p. 2–3. Criticism of IPRs does not always speak for distortion of public interests, but it also echoes the interests of various groups that would benefit from free access to protected materials.
[18] This course of interpretation has its roots in the property rights doctrine. The main rule of IP regulations is exclusivity, so derogations from this principle should be interpreted strictly. The CJEU has opened the door for more flexible interpretation of exceptions and limitations in the copyright case C‑201/13 *Deckmyn* v. *Vandersteen* (2014). It has been concluded that the narrow interpretation rule cannot always be applied. It has also been argued that the interpretation should not be particularly narrow just like exclusive rights should not be excessively wide. Each should have the meaning and scope that was intended for them. This would be especially true for cases where the competing interests are fundamental rights. The CJEU has also given a wide interpretation to the exception to

exceptions. Recent trends in law and politics have called for more equal treatment to all relevant rights.[19] There are often important public interests behind the limitations, so it might not always be justified to presume priority of IPRs whenever a use does not fall within the very core of the exception. This phenomenon has been especially visible in copyright, where the public has increasingly experienced that the scope and duration of copyright does not correspond current values.[20]

Patents have been subject to similar criticism, although not as visibly as copyright. Rather, the public concerns relating to patents have materialized in the form of competition law measures and abuse allegations.[21] Competition interests are important grounds for limiting the exercise of patent rights.[22] However, they are just one way of limiting possible harmful side effects of extensive IP protection. The most traditional way would be not granting patents to inventions that might have socially hazardous effects. Such exclusion from patent protection applies e.g. to "immoral" inventions like commercial applications of human embryos.[23]

More flexible balancing results when only patent enforcement is subject to limitations. It is a classical question whether the grant of (intellectual) property rights should be limited or whether just the enforcement of those rights should be limited. Nowadays the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) forbids the categorical exclusion of pharmaceuticals from patentable subject-matter, so the consideration of public interests inevitably shifts towards the exercise phase.[24] In addition to competition law measures,

---

patentability in Article 6(2)(c) of Directive 98/44/EC in case C-34/10 *Brüstle* v. *Greenpreace* (2011) based on moral and ethical arguments. Thus, there seems to be room for questioning the narrow interpretation rule also in patent law. See Peukert 2015 p. 145–146, European Copyright Society 2015 p. 133.

[19] Oesch 2017 p. 8.

[20] *Id.* p. 10; Oker-Blom 2013 p. 1356–1357.

[21] See Hervey & McHale 2015 p. 278–281 for examples of European competition law actions concerning pharmaceutical patents.

[22] This is because IPRs give the rights holder a chance to monopolize the invention. Even though this monopoly would be limited in scope and time, the adverse effects of such market setting need to be minimized. This is done by applying behavioral requirements on the patentee so that IP protection does not excuse grossly anti-competitive practices. However, in practice most patents do not result in a monopoly, because there are substitutive, competing products. The problem of monopolies is usually only activated in the context of standard essential patents and pharmaceutical and biotechnological inventions. See Matthews & Gurgula 2016 p. 666; Minn 2018b p. 109; Kathuria & Lai 2018 p. 358.

[23] This exclusion can be found in Article 6(2)(c) of Directive 98/44/EC on legal protection of biotechnological inventions.

[24] According to TRIPS, patents must be available in all fields of technology. However, some countries have set up some limitations by introducing different definitions of e.g. novelty or inventiveness. See e.g. Sellin 2015 p. 465–466.

limitations can be imposed on patent enforcement by reserving injunctive relief to cases where it does not significantly interfere with public interest. A more robust measure would be to issue compulsory licenses.

The EU is a direct signatory of TRIPS, so Member States are not allowed to interpret it differentially from the statements of the Court of Justice of the European Union (CJEU). The TRIPS Agreement is governed by the World Trade Organization (WTO) and thus is part of a larger framework. TRIPS covers all central aspects of IP, from grant to enforcement. As a result of this, patent law is increasingly not just national law, although granted patents remain national. Thus, it is not that simple to change any core aspects of it, although some national margin of appreciation remains. In addition to this wide harmonization, IP also enjoys human rights protection as a form of property. As a first conclusion, patent rights are very established, uniform and highly esteemed in the EU.

2.1.2 Intellectual Property as Human Right

Property, including IP, is protected as a human right in various human and fundamental rights instruments.[25] One of these is the Article 1 of Protocol 1 (P1(1)) of the European Convention on Human Rights (ECHR), which grants the right to peaceful enjoyment of possessions. The status of IP as a human right and a non-discriminable form of property has been established in the practice of the European Court of Human Rights (ECtHR), but sometimes the nature of IP can be a decisive factor in the case.[26] IP has gained a strong legal protection in part because it is protected under the general property clauses. A weaker form of IP protection is also found in the International Covenant on Economic, Social and Cultural Rights (ICESCR).[27]

[25] Mattews 2015 p. 497. In older literature the fundamental rights protection for IP was mostly framed through effective legal remedies and fair trial instead of pure property protection. Despite this it was recognized that courts must consider the fundamental rights aspects when deciding IP cases. See Norrgård 2002 p. 56–57.

[26] Geiger & Izyumenko 2018 p. 78. For example, whether copyright exists will be established by a court and the court has the authority to interpret the threshold of originality according to its own standards. Thus, if the court says that no copyright exists, there can be no infringement or violation of P1(1). In the case of physical property, no similar "pseudo rights" occur. In addition, the ECHR and the CFR do not protect a right to acquire either physical or intellectual possessions. See Peukert 2015 p. 137.

[27] Article 15(1)(c) ICESCR protects the moral and material interests of authors in their scientific, literary or artistic productions. This does not correspond to modern patent protection, but it confirms that the interests of the inventor must be balanced with those of the public in access to the invention. Hestermeyer 2007 p. 158.

Failure of states to provide effective means to enforce IP has been considered a violation under both P1(1) and Article 6 of the ECHR.[28] Some have expressed fears that the human rights protection of IP would make its protection unpractically wide and hinder application of useful limitations. So far such fears have not materialized, and it is likely that the ECtHR would allow limitations in the name of public interest – after all, IP exists to serve a social function and not just economic interests.[29] Like many other human rights, it can be limited proportionally on acceptable grounds.[30]

Protection of IP is also part of the EU legal order through the EU Charter of Fundamental Rights (CFR), which is assigned the same value as the Founding Treaties.[31] Its Article 17(2) states that intellectual property shall be protected. This provision has been criticized because of its ambiguity, but the CJEU has been able to shed some light on its meaning.[32] In its case law concerning copyright infringements on the internet, the CJEU has referred to Article 17(2) and stated that it does not mean that IP protection should be absolute, but that it should be proportional and subject to a fair balance with other interests.[33] This is consistent with the conclusions made from general human rights law. Human rights protection of property does not "imply a specific scope of IP protection".[34]

Yet, the line of argumentation that the CJEU has adopted puts emphasis on the various obligations for IP protection resulting from international treaties and EU instruments. This tends to happen at the cost of utilizing the options for limiting IPRs. These options to limit are also an integral part of IP legislation. This results in gradual strengthening of IPRs and dilution of the exceptions.[35] This is curious taking into account the general trend of enhancing human rights protection. One would imagine that the various limitations of IPRs would be very important in that respect. Also the role of the EU in the IP field has become very central and EU-related IP

[28] Geiger & Izyumenko 2018 p. 76. Article 6 ECHR contains the right to fair trial.
[29] Geiger & Izyumenko 2018 p. 77; Mattews 2015 p. 498; Mylly 2009 p. 27.
[30] Hestermeyer 2007 p. 152. However, IPRs are also treated as "rights" instead of just property, which means that "social utility alone is not reason enough to override it." This has an effect on which public interests are acceptable for limiting use of IP. See Merges 2011 p. 261.
[31] This is a central part of the developments that have increased the importance of human rights, including IP, in the EU. This trend was especially due to the adoption of the Lisbon Treaty, including the TFEU and the CFR. See Walkila 2011, Walkila 2015b p. 794.
[32] Grosse Ruse-Khan 2015 p. 72.
[33] *Id.* p. 73–74. See cases C-275/06 *Promusicae* and C-70/10 *Scarlet Extended*.
[34] Peukert 2015 p. 142.
[35] Grosse Ruse-Khan 2015 p. 78.

instruments have gained primacy in many respects. In such a setting any national amendments to the content of IPRs could be a violation of CFR Article 17(2).[36]

2.1.3 Intellectual Property as Entitlement

IPRs are also a form of entitlement. Like other entitlements, there are two fundamental ways in which they can be protected. These are the property rule and the liability rule. Under the property rule, the owner has the sole discretion to decide on the use of the asset. They are free to decline others the right to engage in certain actions in relation to the asset. In the case of IP, injunctions are the enforcement tool mirroring this concept. The liability rule, on the other hand, means that anyone can engage in protected actions if they are willing to pay a price. The price is determined by a third party, in patent cases e.g. by a court setting the royalty rate. The owner of the asset does not have the right to exclude others; they merely have a right to get paid.[37]

It is a long-standing debate of the IP field whether IPRs should be governed more by the property rule or the liability rule. Traditionally, the property rule has played a major role and injunctions have enjoyed a central position in the enforcement palette. Reasons for this include the difficulty of estimating the value of different kinds of IP as well as the fact that IP is non-rivalrous and can easily be undermined if there is no effective legal protection.[38] Those who favor the liability rule emphasize the inefficiency of licensing schemes when there are multiple stakeholders involved. Also the hold-up problem has been discussed a lot in this context. It refers to using the threat of an injunction for pressurizing into unreasonably high license fees.[39]

It has been argued that liability rule would be much more efficient and proportionate for copyright, if the ultimate aim is to secure an appropriate income for creators.[40] For purely this purpose, a right to get paid might be more suitable than exclusivity. The liability rhetoric has gained more ground recently also in patent cases, especially in the USA because of the *eBay* judgment.[41] This has led to differential application of the liability and property rules according

---

[36] Grosse Ruse-Khan 2015 p. 78. However, it can also be argued that the national margin of appreciation is actually quite wide from the perspective of fundamental rights. According to this view, the legislator has wide discretion to set the exact scope of IPRs as long as the required minimum level is maintained. Current protection has much extended from that minimum. See Peukert 2015 p. 144–145.
[37] Seaman 2016 p. 1954–1956. In copyright a liability rule concept is in use through collective rights management.
[38] *Id.* p. 1956–1957.
[39] *Id.* p. 1957–1958.
[40] Mylly 2015 p. 109. Copyright is already largely managed though collective societies that grant a license to anyone who is willing to pay an appropriate fee. Still, the starting point in legislation is the right to exclude.
[41] Seaman 2016 p. 1959. See case 547 U.S. 388 *eBay* v. *MercExchange* (2006).

to the status of the parties and the industry they represent.[42] The relationship of property and liability rules in the context of pharmaceutical patents is very central for this study.

2.2 Right to Exclude as a Fundamental Right of the Patent Owner

2.2.1 Exclusion as the Core of a Patent

Traditionally IPRs equal a right to exclude. According to Article 28 of the TRIPS Agreement, patent owners have exclusive rights to prevent others from using the patented invention. These rights take their most concrete form in an injunction, which judicial authorities must have an authority to issue in response to patent infringement (Article 44 TRIPS). The exclusive rights can be subject to limitations as long as they "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" (Article 30 TRIPS). Since the "exclusive right to prevent" is virtually the only right granted to patent owners, it seems justified to call exclusion the core of patent law.

But what is the status of the right to exclude under the human rights protection of IP? In human rights discourse calling something the core of a right implies that there would also be a more relatively protected "rest". This idea of a non-negotiable core of human rights can be extracted from the practice of the ECtHR.[43] Yet, it is not simple to distinguish the absolute core from this "rest". Literally interpreted, the core of a right would be the part that cannot be limited in any circumstances, whereas the rest would be protected relatively depending on circumstances and subject to balancing with other interests.[44] In human rights language, calling right to exclude the core of patent law would imply that this right cannot be substantially limited. At the same time it is quite clear that patents do not belong to the category of absolute rights, nor is the right to exclude absolute, although traditionally very strong.[45]

The ECtHR also supports a relative interpretation of the very essence of rights, so the extent of protection may depend on circumstances.[46] Since protection of IP is part of the protection of property, it seems more likely that the ECtHR would interpret the core from the perspective of

[42] *Id.* p. 2006.
[43] Christoffersen 2015 p. 26.
[44] *Ibid.*
[45] *Id.* p. 27.
[46] *Ibid.*

the entire Article. This core would most likely be something about illegitimate deprivation of property, for example sudden nullification of patents. This would be a violation of a different level than mere limitation of exclusivity. At this stage I simply note that public interest in health rights might be an acceptable basis for limiting patent rights independent of any core status of exclusivity, because health rights are also human rights and thus neither necessarily enjoys primacy over the other. The appropriate balance depends on the circumstances.

There are also scholars who think that the right to exclude is actually not necessary or central to a patent. Rather, it is an "incident" following from the "privilege" of use that the patent encompasses.[47] The idea of a privilege is consistent with the historical background of patents not as subjective rights but as tools to promote public interests of the geographical area.[48] From the privilege perspective it would be easier to justify limitations to patent enforcement, because then there would be no direct interference with any alleged fundamental rights. The right to exclude is a traditional and fundamental part of current patent protection, but it might not be absolute or necessary in all circumstances.

2.2.2 Balancing with Public Interests

Patent law as a whole is no stranger to balancing public interests: the very idea of a patent is to grant temporally limited exclusivity in order to promote innovation and knowledge-sharing.[49] Yet, patent laws traditionally do not refer to public interests or any form of general balancing. They merely grant rights to the patentee. As can be seen from Article 30 TRIPS, exceptions to the right to exclude are subject to quite strict scrutiny.[50] This might be part of the reason why TRIPS has been criticized of constantly widening the scope of IP protection.[51] This is the case

[47] Gervais 2015 p. 96.
[48] Hestermeyer 2007 p. 21. Patents have their background in privileges granted by the state. They were not subjective rights of the patent owner. Rather, the goal was to promote introduction of new technology to the society, and the privilege guaranteed that the invention was published so that new innovation could be built upon it. The notion that the inventor has a right to a patent is relatively new.
[49] Sellin 2015 p. 462.
[50] For example, according to established interpretation, the limitedness of exceptions should be evaluated in terms of how they limit the exclusive rights, not the economic impacts of the exception. Also, only interests of the patent holder are considered under “normal exploitation” and it seems that the patentee is likely to prevail if they have any compelling interest in keeping the invention exclusive. Hestermeyer 2007 p. 235–237.
[51] The widening is also a result of so-called TRIPS Plus Agreements the aim of which is to extend the rights of the patentee from those guaranteed by the TRIPS. These have been perceived to act especially in the benefit of multinational pharmaceutical companies. See Helfer & Austin 2011 p. 125.

even though the TRIPS Agreement does not solely promote interests of the inventor, but also calls for a balance of rights and obligations (Article 7 TRIPS).[52]

Article 8 of the TRIPS Agreement mentions that measures may be adopted to protect e.g. public health, but only so far as such provisions are consistent with TRIPS. This is not a general exception clause, but it can guide the implementation and interpretation of the Agreement.[53] This was also stated in the 2001 Doha Declaration,[54] which included the statement that the "TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".[55] Thus, states have definitely not intended to set IP above other societal interests, although this has sometimes appeared as a consequence of the robust enforcement mechanisms provided for IP and under the WTO framework.

Enforcing a patent is a fundamental and legitimate right. As such it cannot be extensively limited or considered abusive, although patent enforcement may sometimes undermine developments that the society perceives as beneficial. It is a different matter if a company tries to e.g. misleadingly enforce expired patents with the aim of preventing competition.[56] Exclusivity is the natural benefit coming with a patent. This is the case despite the fact that the liability rule (right to get paid) has been gaining more attention in certain industries and jurisdictions. Such developments have been visible e.g. in collective copyright management for a long time, but for patents exclusivity still contains important value and patents (like other IP) are still defined through it in international treaties and national laws.

Under the ECHR, IP can be both protected from interference but also limited in relation to other, more important rights.[57] For example, the European Commission of Human Rights (ECommHR; predecessor of the ECtHR) has found the grant of a compulsory license for a

[52] The TRIPS Agreement contains several flexibilities that can theoretically be utilized to promote public health. These include the objective and principle provisions, exhaustion, exceptions to patent rights and compulsory licenses. See Matthews 2011 p. 17.
[53] Sellin 2015 p. 453–454.
[54] Although the legal power of the Doha Declaration has been questioned. See e.g. Hestermeyer 2007 p. 279–281. There have also been several other decisions that have tried to address the issues regarding strong IP protection and public health.
[55] Doha Declaration para. 4.
[56] Some scholars have argued that competition law should be used more vigorously in cases that exhibit anti-competitive features. Even when the employed strategies are as such lawful, their anti-competitive aims and harmful effects should give cause for interference. See den Exter 2010 p. 128; Matthews & Gurgula 2016 p. 666.
[57] Grosse Ruse-Khan 2015 p. 79.

pharmaceutical patent lawful when pursuing other important interests in a proportional manner.[58] This is interesting for the topic of this thesis, because it confirms that the use of IP can be substantially limited without violation of the fundamental rights of the IP owner. In a way, the key is proportionality and balancing of the conflicting interests. The graver the public need for the use of IP, the larger interference can be justified.

The requirement for proportionality and least restrictive means is highlighted in the ECtHR case *Balan* v. *Moldova* (2008), where the author's legally recognized copyright had been violated, when the state had printed a photograph on ID cards without permission. The state should have respected the IP of the author, and it could have easily asked for a permission or picked another photograph had the author refused.[59] Thus, the public interest in the use of the photograph did not prevail over the author's IPR. The national courts had "failed to strike a fair balance between the interests of the community and those of the applicant, placing on him an individual and excessive burden".[60]

Drawing from this, it is clear that not all kinds of public interests are important enough to justify overriding the right to exclude, even if there are some that do. The public interest argument is not a discussion stopper that can be used by states to allow IP infringements when it is convenient for the public. This would constitute a violation of P1(1). The extent of interference must be proportional to the graveness of the public interest. This is in line with the initial idea that public health interests might sometimes entitle the court to deny a pharmaceutical patent injunctive relief. However, the bar for justified interference is set quite high and one might argue that it is practically never exceeded in developed countries that have a steady supply of essential medicines. Before considering health rights in more detail, the topic of exclusivity will be discussed specifically from the perspective of the pharmaceutical industry.

[58] *Smith Kline and French Laboratories Ltd* v. *the Netherlands* (1990).
[59] Grosse Ruse-Khan 2015 p. 80–81.
[60] *Balan* v. *Moldova* (2008) para. 46. In this case it was clear that the state had other options. The interest in using that particular photograph could not be very material. Same cannot be said in all cases that involve public health.

2.3 Exclusivity and Implications for Pharmaceutical Patents

2.3.1 Realities of Innovative Pharmaceutical Business

Pharmaceuticals are a societally important and economically valuable market both globally and in the EU.[61] The industry is known for extremely high R&D costs: bringing to market a new drug can cost over $2.5 billion.[62] Then again, pharmaceuticals are also extremely profitable.[63] The industry is very competitive, although risky because of the uncertainty related to development of new drugs.[64]

Patents are important assets for innovative pharmaceutical companies for the protection of their novel products. Patent rights are meant to reward innovators, but also to encourage further innovation. To balance the reward of an exclusive market with public interests (such as effective competition), the period of patent protection is temporally limited to 20 years.[65] This period must be put to use effectively by pharmaceutical companies to cover the costs put to R&D.

Pharmaceutical patents and the practices of innovative pharmaceutical companies have attracted lots of criticism over the years. One perspective has been that public health interests are too important to be even theoretically exposed to abusive monopolies. For this reason, many countries used to not allow patent protection for pharmaceuticals, at least not directly.[66] Since then the situation has changed, and patents must be available in all fields of technology (Article 27(1) TRIPS). The change was less welcome in countries that had strong public policies promoting access to medicine, such as India.[67] States can no longer sovereignly control all policies that affect access to medicines. Part of that control is in the hands of pharmaceutical companies and their business decisions.[68]

There are practical reasons why pharmaceutical patenting is also promoted. Some have even argued that pharmaceuticals are one of the few businesses genuinely in need of exclusive

[61] den Exter 2010 p. 125; Tuominen 2012 p. 541–542.
[62] Stiefel & Carter 2016 p. 1.
[63] den Exter 2010 p. 127–128.
[64] Helm 2009 p. 39.
[65] Minn 2018a p. 17.
[66] Boscheck 2015 p 222. An example of indirect patent protection is the Finnish analogous process patent that allowed the protection of a process for the manufacture of a novel pharmaceutical. The same product could be manufactured without infringing the patent by a process not described in the patent. Before 1995 this was the only form of patent protection available for pharmaceutical products in Finland. See Norrgård & Bruun 2007 p. 697.
[67] Matthews 2015 p. 500–501.
[68] Lee & Hunt 2012 p. 220–221.

rights.[69] Pharmaceutical development is tremendously expensive, especially in the clinical trials phase. A big portion of the patent term goes to waste because of the long authorization procedure, and even supplemental protection certificates (SPCs) cannot completely compensate for it. Once the pharmaceutical has been granted a marketing authorization, it is often relatively cheap to manufacture.[70] Without patent protection, any company could start copying the product, pulling the price down and taking a market share away from the originator company. As a result, there would be no way to recover the costs put into the research and authorization phases. This would strongly discourage innovation.[71]

This is why big, innovative pharmaceutical companies tend to focus in their patent strategies to the maintenance of exclusivity for their key products. In short, exclusivity is needed to make the R&D investments worthwhile. These companies have many kinds of strategies dedicated to this aim, from patenting practices to use of administrative procedures and patent enforcement. Some of these tactics have also raised controversies. The Commission has condemned some of them as anti-competitive or abusive,[72] but this does not apply to the entire business or all companies.

R&D of innovative companies traditionally focuses on so-called blockbusters, which are patented, bestselling products aimed at a large population.[73] For many years experts have predicted the downfall of the blockbuster business model and a shift towards more personalized treatments and biological medicines that are harder to copy and reproduce.[74] All these predictions have not come true yet, and even if they do, patent expiry and circumvention remain a relevant issue for innovative companies.[75] Overall, innovative pharmaceutical business is very dependent on patents and the exclusivity they provide.[76] The dependency on patent protection makes it crucial for innovative companies to have effective enforcement practices.

---

[69] Posner 2012.
[70] This, of course, depends on the product. Small-scale production can remain expensive.
[71] Posner 2012.
[72] See e.g. case C-457/10 P *AstraZeneca* v. *Commission*.
[73] den Exter 2010 p. 127–128.
[74] Song & Han 2016 p. 3. However, patents on complex biological products can also be hard to defend because of the variety of starting materials and methods of measurement.
[75] McDermott 2012 p. 25.
[76] With this in mind, many pharmaceutical companies have honed their innovation processes so that they are able to patent improvements of existing products (called follow-on patents or second generation patents) and thus benefit from multiple overlapping patent terms. Especially some generics companies have argued that these patents do not actually benefit the society and merely exist to maintain exclusivity and high profits for innovators. This is not the whole story, though, since second generation pharmaceuticals often exhibit important improvements that produce

2.3.2 Enforcement Practices of Innovative Pharma

Because of the limited patent term and large costs of product development it is important for innovative pharmaceutical companies to maintain an exclusive market for as long as possible. For many big, innovative pharmaceutical companies it is an established strategy to use the available means to exclude competition and keep generic products out of the market.[77] For this aim, they employ a broad range of tactics, vigorous enforcement being one of them.[78] Enforceability is a central aspect of a patent's value – and thus also the company's value.[79]

When the goal is to exclude, it is no surprise that pharmaceutical patent owners turn to litigation if negotiations and warning letters fail. It is common to apply for a preliminary injunction, because if an infringing product makes it to the market, effects on the patentee can be huge.[80] There is even a term for the effects caused by market entry of generic products: "patent cliff" refers to the resulting fall of market share and product price.[81] This occurs naturally at the time of patent (or SPC) expiry, but it can be advanced if infringing products are allowed on the market. This is why patent owners are very eager to stop infringements at an early phase, preferably before market entry. Thus, it can be a normal strategy to take infringement cases to court very quickly upon detection.

Of course, when speaking of patent disputes, it must be kept in mind that only a small portion of the actual disputes end up with a court judgment. Many cases are settled, so only in a limited amount of cases the court has had the possibility to state something about injunctive relief. Typically, when both parties have a similar idea of what the court would decide, the willingness to settle increases.[82] In those cases that do end up in court, the goal is often to obtain an

---

value for patients. Moreover, the patent system is also meant to promote minor improvements and not just revolutionary discoveries. Ng 2009 p. 459; Helm 2009 p. 40–41, 50; Golden 2014 p. 2114–2115.

[77] Pharmaceutical Sector Inquiry 2009 paras. 540-541.

[78] Matthews & Gurgula 2016 p. 665; Song & Han 2016.

[79] The real value of a pharmaceutical patent often does not lie in its basic economic value. Instead the big deal is the leverage it gives, in practice the right to exclude competition and to set prices, and the threat of litigation. It is thus not just about the quality and technological significance of the patent. Minn 2018a p. 18; Feldman & Price 2014 p. 794.

[80] den Exter 2010 p. 132.

[81] Broes et al. 2016 p. 21.

[82] Seaman 2016 p. 1980. This is also visible in how litigation concerning a particular product can be running in many European countries simultaneously, but when a few judgments have been given the remaining cases are often settled.

injunction that allows exclusion of the infringer. Also in settlements innovator companies tend to pursue continuance of their exclusivity.[83]

All in all it can be said that injunctions are a valuable tool for innovative pharma. They are in practice the only tool that reserves the market for the innovator and allows effective exclusion of infringers. In the traditional business model licensing is quite rare and companies resort to their right to exclude. The availability of injunctions is thus a topic of central interest to these companies, since it can have long-term effects on their business models and profitability. With this background knowledge of IP and the pharmaceutical industry, we move on to discuss the content of health rights and their relationship to patents.

3. Health Rights and Coexistence with Patent Law

3.1 Health Rights in Legislation

3.1.1 International Health Rights Framework

Health rights are a group of health-promoting human rights resulting from various international treaties. The Constitution of the World Health Organization states in its preamble that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being" and defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". According to Article 25(1) of the Universal Declaration of Human Rights, "everyone has the right to a standard of living adequate for the health and well-being of himself--, including -- medical care --".[84] The International Covenant on Economic, Social and Cultural Rights (ICESCR) sets in its Article 12(1) the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health". Also many national constitutions ensure some level of health protection.[85] In instruments that do not directly mention health the right to health is covered under the right to life. This is the

[83] This has raised controversies especially in the context of so-called reverse payment or pay-for-delay agreements, where the patent holder pays another company for not infringing their patent. Sometimes the patent might have already expired, so the company actually pays for the delay in getting competition. Such arrangements have woken the attention of competition authorities for their anti-competitive nature. See Minn 2018b and Matthews & Gurgula 2016 p. 664.
[84] A similar right is also conferred in the European Social Charter.
[85] Lee & Hunt 2012 p. 220.

case with the ECHR.[86] The ECHR also mentions protection of health as acceptable grounds for interference with certain human rights.

According to the authoritative interpretation of the Committee on Economic, Social and Cultural Rights (CESCR), the ICESCR right to health contains the aspects of availability, physical and economic accessibility, acceptability (ethics) and quality of healthcare.[87] It does not mean a "right to be healthy", but it does contain an entitlement to health protection.[88] More concretely, this protection includes concepts like access to medicines and access to healthcare.[89] An obvious weakness is that the international human rights framework is poorly enforceable, for it only contains a soft monitoring and reporting mechanism. This is noteworthy, because the WTO framework – including TRIPS – is subject to an effective dispute settlement mechanism.[90]

Access to essential medicines is a universal human right.[91] That is the rigid core of the right to health.[92] On a global scale it is rather poorly realized. An immense amount of people do not have regular access to medicines.[93] From global perspective the role of patents in this equation has been somewhat controversial. It is quite clear that patents increase prices of pharmaceuticals, but this is just one part of the wide issues affecting access to medicine in developing countries. In these countries there are typically also problems with healthcare infrastructure, resources and corruption.[94] If the main issues are due to larger societal problems, the question of patent enforcement is rather secondary in the big picture. This is why developing countries are not discussed extensively in this analysis.

---

[86] The ECtHR considers violations of health rights under Article 2, the right to life, because the ECHR does not mention a right to health. For example cases of medical malpractice have been heard under Article 2. See e.g. ECtHR case *Lopes De Sousa Fernandes* v. *Portugal* (2017) para. 165. This is a form of implicit human rights protection. See Neuvonen & Rautiainen 2015 p. 32–36.
[87] CESCR 2000 para. 12.
[88] *Id.* para. 8.
[89] According to Shadlen, the availability and accessibility of pharmaceuticals is indispensable and cannot be substituted by any amount of healthcare. Shadlen et al. 2011 p. 14.
[90] Sellin 2015 p. 453.
[91] WHO: Essential medicines and health products. The international conventions only explicitly protect access to essential medicines or access to life-saving medicines. See Hestermeyer 2007 p. 136.
[92] CESCR 2000 para. 43.
[93] Sellin 2015 p. 446.
[94] *Ibid*. Also these countries typically suffer from lack of classical essential medicines, most of which are not protected by patents. See Civan 2008 p. 11. In some cases the issue may also be that relevant medicines do not simply exist. Their development would not be profitable for pharmaceutical companies, because the affected people would be unable to pay for expensive new treatments. These cases are called neglected diseases. They mean diseases that are either too rare to be profitable or that only affect people in poor countries. See Sellin 2015 p. 447.

Recently, as the general human rights standards have raised, health rights have attracted more attention also in the EU and other developed countries. For example, it has been noted that even though common and essential medicines are widely available, not all patients might have access to them because of their financial situation.[95] There are also many new treatments that could benefit patients but that are not accessible to patients for administrative or price-related reasons. For the administrative part, there are programs that try to facilitate timely access of patients to novel treatments by offering a progressive authorization procedure.[96] Financial reasons are harder to address, because they depend on each state's healthcare system and policy.

While the right to access essential medicines is widely recognized, it is much more controversial whether access to novel medicines also belongs to the human rights framework. Novel medicines are generally well available in developed countries, but many people do not have access to them because of high prices.[97] This includes both cases where the patient cannot afford an out-of-pocket payment and cases where the national health system cannot afford to offer a particular treatment to its users.[98] Such high prices have been statistically connected to patent protection.[99] The health benefits of novel treatments are attainable in the EU in the literal sense,[100] but it might not be a violation of the right to health to not have access to them. This dilemma will be further elaborated in forthcoming sections.

3.1.2 Content of European Health Rights

In the EU, health rights can be derived from human rights instruments as well as the founding treaties. According to Article 168(1) TFEU, "a high level of human health protection shall be ensured in -- all Union policies and activities". On the other hand, Article 168(7) TFEU states that the "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care". In practice this means that the Member States have quite a lot of discretion in how they organize

[95] Minn 2018a p. 16.
[96] See EMA: Adaptive pathways. Adaptive pathways are a set of tools that make it possible for patients to access novel treatments that have not gone through the entire authorization procedure yet e.g. because clinical trials are hard to conduct because the relevant patient population is so small.
[97] Minn 2018a p. 16. In this respect the situation in Europe is not as bad as e.g. in China, where medicines are also well available but too pricy for most patients. See Watanabe & Shi 2011 p. 280–282.
[98] Owoeye & Owoeye 2018 p. 51.
[99] *Id.* p. 52.
[100] Referring to the "highest attainable level of health".

their health systems and enable access to health.[101] What the Article reinsures from an EU perspective is that health is a relevant interest that can be taken into account in EU decisions and policies.

On the human rights side, health rights are set in Article 35 of the CFR. According to the Article, "everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices". The Article also echoes the same EU policy statements as Article 168(1) TFEU. It does not directly give an individual the possibility to question national healthcare policies, but leaves the ultimate choices to the Member States.

The adoption of the ECHR and the CFR – the concrete and legally powerful instruments – has improved to status of human rights as part of the substantive, applicable law. The role of human rights remains on the rise in the EU: the CFR has the status of primary law and the EU is looking to join the ECHR as an official party.[102] Thus, the effect of human rights on all fields of law can only increase in the near future.[103] The Commission has recognized health as a human right and the importance of having an EU health policy in order to respond to current health challenges.[104] Health has thus gained a more concrete and independent position in EU law instead of being merely a general principle rising from the ECHR and constitutional traditions.[105]

The pharmaceutical market in the EU is very fragmented due to different national policies and the variety of products for different conditions.[106] As a consequence of this and the available tools, the proprietors of novel pharmaceuticals have the chance to maintain a strong exclusive position in their relevant product markets. Profitable product prices are determined by the expenditure of the development process. In practice this means that medicines can be available in the EU, but the market setting contributes to high prices, which diminishes actual access.

---

[101] This is consistent with the traditional interpretation of the content of social rights. Neuvonen & Rautiainen 2015 p. 49.
[102] Walkila 2015b p. 794–799. All the Member States already are parties.
[103] Smith 2015 p. 55. It has even been noted that the high standard of human rights within the EU framework could operate to raise the overall bar for human rights compliance. The level of human rights protection required under the ECHR is minimum protection, but the interpretations of the ECtHR tend to assume a quite high level of protection, because the interpretations are context-dependent. If the general standards rise too high, it might cause difficulties for less developed countries. Smith 2015 p. 60.
[104] White Paper 2007.
[105] Hervey & McHale 2015 p. 160–166.
[106] Tuominen 2012 p. 541.

Proprietors also have a lot of discretion as to which markets to enter, so a novel pharmaceutical might not be available in all Member States. Negotiations with national authorities over the reimbursement status of a product determine the consumer price and also give the companies some prospect of which markets will be most profitable. The outcomes of these negotiations are influenced by local health policies and priorities.[107]

A very difficult question for the EU is how it can promote both access to medicines and innovative pharmaceutical business. It seems that increasing access to medicines will almost directly decrease incentives for pharmaceutical innovation. Then again, in the long run innovation will improve effectiveness and availability of different medicines.[108] The picture is even more complex than this. Patent – and more broadly IP – policy must be reconciled with sustainable development of the society as a whole, this including cultural, social and environmental objectives. The role of IP in these efforts should also be viewed critically.[109] Strengthening of human rights is a trend visible in many EU policies and it is reasonable to assume that health, too, will gain even more ground as an independent value in the future.[110] An eye should be kept on how this will combine with the promotion of IP protection and pharmaceutical innovation.

[107] Minn 2018a p. 17; Tuominen 2012 p. 542–543; Nyblin 2009 p. 917. According to some, the national authorities are very strict regarding product pricing, so there would be no room for excessive profits. The role of patents in this equation is not simple, but their role as incentives must not be understated. For example Nyblin sees IP protection – in addition to reimbursement questions – as a fundamental piece in the overall puzzle that determines which pharmaceutical products are available to patients.

[108] den Exter 2010 p. 127.

[109] This is an issue especially in developing countries, where promotion of trade-related rights more directly contradicts efforts aiming for sustainability and social justice. Health rights are an ethical and not just a financial consideration. Overall, the question of access to medicine is tightly coupled to the wider issue of sustainable development and its relationship to IP. Similar rhetoric of regulating IP for the benefit of societal aims has been presented in the context of climate issues. It has been argued that climate-friendly inventions should merit more beneficial treatment and patentees in general should have more social responsibilities. This is an example of using the patent system to promote goals that have not been incorporated into traditional patent laws. See Elmahjub 2016; Carbone 2003 p. 215; Derclaye 2009.

[110] However, some might question the value of providing separate health rights protection and would emphasize the use of general human rights principles instead. In some cases restraining from formulating explicit human rights may provide more flexibility. Thus, one might argue that any debate whether there is a "right to access novel medicines", for example, is unnecessary and courts should merely make case-sensitive conclusions. See Neuvonen & Rautiainen 2015.

3.2 Conflict of Fundamental Rights?

3.2.1 Conflict or Coexistence?

This section discusses the extent of the conflicts and tensions between patents and health rights. Both IP law and human rights law have significantly strengthened and widened in scope in the past decades.[111] Traditionally they have been perceived as isolated bodies of law, but along with their spreading interaction has become inevitable.[112] IP is now incorporated into the frameworks of the WTO with the TRIPS Agreement, which has become a fundamental treaty governing essential features of IP. At the same time, human rights documents have increased their importance both nationally and internationally. In Europe, the ECtHR is an important source of case law.[113] The CFR has gradually become a significant reference point for the CJEU, [114] which has begun to employ human rights argumentation in its judgments[115] also in IP cases.[116] Peaceful approximation of these two fields would require symbiotic use of both of them, but the international trade community has been quite reserved in including human rights or social justice arguments into its discourse.[117] On the other hand, human rights promoters have put a lot of effort in criticizing pharmaceutical companies and wide patent protection without properly giving credit to the legitimate interests of IP holders.

It is a long-standing debate whether human rights and IPRs are essentially in conflict or whether they complement each other.[118] Conflict does not merely refer to the incompatibility of some provisions, but it also covers more general tensions, like promotion of one goal at the expense of another.[119] The UN human rights system has sometimes endorsed the conflict approach being of the view that IPRs essentially stand in the way of realization of economic, social and cultural rights, including health.[120] Conflicts with rights to health and life are seen to arise as a result of extensive pharmaceutical patent protection.[121] As a solution it has been suggested that human

[111] Helfer 2015 p. 7.
[112] *Id.* p. 6.
[113] *Id.* p. 7.
[114] Smith 2015 p. 56; Walkila 2015b p. 794–795.
[115] Raitio 2013 p. 345–350.
[116] Mylly 2015 p. 103.
[117] Sellin 2015 p. 447–448.
[118] Helfer 2015 p. 11; Hestermeyer 2007 p. 182.
[119] Sellin 2015 p. 449.
[120] Helfer 2015 p. 11.
[121] Sellin 2015 p. 448.

rights be raised above property rights in international law[122] – a primacy not officially in place.[123] Although health rights can be valued morally superior to property rights, their enforcement possibilities remain weak and they cannot be said to have gained a *jus cogens* status.[124]

According to the coexistence doctrine, human rights and IPRs inhabit the same field and strive towards solving the same problems, but they tend to draw somewhat different conclusions. The tension lies between simultaneous promotion of exclusivity (representing the incentive to create and innovate) and access of public to the creations and innovations.[125] This approach recognizes that IP serves a social function and thus the interests of private authors and inventors should be balanced with those of the public.[126] To reach this aim, it is crucial that the applicable exceptions and limitations are flexible, appropriate in scope and properly utilized.[127] This might not always be the case, if the fundamental protection of property is interpreted too strictly or the minimum level of IP protection is strengthened by only considering interests of the right holder.[128] In current international law, the coexistence approach is widely accepted and the presumption is usually against conflict.[129]

3.2.2 Different Natures of Patents and Health Rights

Even though both patents and health rights are recognized as legitimate interests and fundamental rights, it should also be noted that their natures are essentially different. Patent law, being more robust and enforceable, should perhaps incorporate other societal interests as balancing tools. However, the current IPR system was not created with the view of balancing IPRs with (other) human rights.[130] It can thus be questioned whether current patent laws incorporate proper human rights protection. It would seem that application of IP rules requires some balancing with human rights interests, since IP legislation does not as such promote human

[122] Sub-Commission on Human Rights resolution 2000/7 preamble para. 3.
[123] At the moment IPRs and health rights are formally equal, as they are both human rights protected under the ECHR. Sellin 2015 p. 458; Ducoulombier 2015 p. 40.
[124] Sellin 2015 p. 456 and 460. *Jus cogens* refers to non-derogable and superior rules of international law. It contains e.g. right to life (in the meaning of prohibition of killing) and prohibition of torture, which should not be violated under any circumstances. See e.g. Hestermeyer 2007 p. 190.
[125] Helfer 2015 p. 12–13.
[126] CESCR 2006 para. 35.
[127] Helfer 2015 p. 13.
[128] The latter point specifically refers to so-called TRIPS Plus Agreements. See Helfer & Austin 2011 p. 125.
[129] Hestermeyer 2007 p. 182–183.
[130] Helfer 2015 p. 13.

rights aims.[131] A more difficult dilemma is to recognize and agree on when additional balancing is required and when the basic rules provide adequate protection for all interests.

The discussion concerning patents and health rights has perhaps been the most prevalent debate concerning the relationship of IP and human rights.[132] The UN Sub-Commission on Human Rights has specifically stated that the TRIPS Agreement does not currently implement the indivisibility of human rights, including the right to health.[133] These views arose especially in response to the HIV epidemics of late 20th century, where the conduct of some pharmaceutical companies was seen to worsen the situation for patients.[134] This setup awoke many patent-critical voices and has been affecting the public image of pharmaceutical companies even after the incidents.

Drawing especially form this context, it must be admitted that IPRs differ in a few central ways from "basic" human rights, even though they often are guaranteed in the same legal documents. These differences have been extensively pointed out by the CESCR:

> "Human rights are fundamental as they derive from the human person as such, whereas intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits. In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While intellectual property rights may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments."[135]

The core differences can be highlighted as characterizing patents as inherently instrumental whereas health rights are an end in themselves. Furthermore, attention can be drawn to the position of property rights as state-derived and human rights as "natural" or "indispensable". According to some, these differences account for the fact that IP and human rights should not be balanced as if they were equal.[136] Taking into account these core differences, it must be

---

[131] *Id.* p. 13–14.
[132] Matthews 2015 p. 496.
[133] Sub-Commission on Human Rights resolution 2000/7 para. 2.
[134] Ng 2009 p. 458.
[135] CESCR 2001 para. 6.
[136] Peukert 2015 p. 139.

concluded that health interests should sometimes be able to override patent protection and thus restrict the use of IPRs.[137]

Human rights have already affected the scope of IPRs during recent decades, although these effects are not the most prevalent in patent law. Still, patent law is no longer an independent and technical body of law. Human rights concerns have penetrated the IP field with varying degree of strength and must be effectively addressed. It can also be seen as a positive thing that IP law is forced to reconsider and defend the values it represents.[138] In this way, better compromises and more up-to-date rules can be formulated.

3.2.3 Effects of Human Rights on IP Law

Human rights have had various effects on the IP field. There are some that would prefer that the effects remain abstract. This approach treats the ICESCR merely as a guideline or a "promotion for good practices".[139] According to this view, the UN human rights are ill suited for enforcement and should not be used as a basis for litigation. This is because they are both ambitious and ambiguous: Highest attainable level of health is very different for countries with different levels of income. The same standards for assessing adequacy and violation cannot possibly be applied for all countries and yet the ultimate goal should be the same for all, because it is about a human right.[140] Although there is a point in this approach, the notion of ICESCR as mere guidelines has been received with suspicion.[141]

The rise of human rights has made balancing different interests a more frequent task in many fields of law, including IP.[142] This balancing often resembles political decision-making, since it is based on the values of the person striking the balance. There are no absolute rights or wrongs

[137] In the light of the "instrument v. end" comparison it also makes sense that health rights can mainly be enforced only by shaming those who do not respect them, whereas the WTO framework includes effective enforcement mechanisms. If an instrument cannot be used properly, it quickly becomes obsolete. Hestermeyer 2007 p. 203.
[138] Seville 2013 p. 180.
[139] Marks 2016 p. 142.
[140] *Id.* p. 141.
[141] Owoeye & Owoeye 2018 p. 52. However, many scholars are of the opinion that human rights reasoning rarely affects the outcomes of cases. It merely provides an additional layer of arguments, but same conclusions can also be drawn from other legal sources. See Hervey & McHale p. 180.
[142] In addition to explicit balancing, human rights guide the interpretation of all legal provisions by setting boundaries to what the legal system may contain. Ojanen 2014 p. 949.

in where the balance should be.[143] This is why the balancing questions cannot be answered just by legal dogmatic but require a law and politics approach and deliberate choices.

According to Matthews,[144] the effects of human rights on the IP field can be divided into three thematic clusters: legislative changes, policy changes and judicial interpretations. Legislative changes cover the implementation of new statutory rules. Sometimes the legislator tries to maintain the previous policy or values despite the change. Such policy maintaining phenomenon was observed in India's implementation of the TRIPS Agreement, which did not allow the complete exclusion of pharmaceuticals from patentability.[145]

Policy changes refer to changes in how public authorities act and what they promote without any legislative changes necessarily taking place. This has happened in Brazil in response to the HIV epidemic and high prices of patented anti-retroviral drugs. The public authorities took a big role in negotiating down the prices of the drugs so that access could be provided for all.[146] Policy changes have also taken place in Europe, when competition authorities have started to react to some anti-competitive practices of pharmaceutical companies.[147]

Lastly, judicial interpretations can change the state of affairs without any official changes in legislation or public policy.[148] This happens by natural or conscious shifts in how existing legal documents are interpreted and valued by judicial authorities. There are numerous examples worldwide how consideration of human rights has changed established case law and given room for new kinds of arguments. The phenomenon has made constitutional and human rights provisions directly applicable in courts.[149] This has also happened in the CJEU's argumentation in IPR cases, especially copyright cases. In patent law it is yet to happen.

---

[143] Christoffersen 2015 p. 37. Even though a human right, health interests must be balanced with e.g. market objectives, resources and other human rights. Health rights generally do not include an entitlement of an individual to a particular treatment. See Hervey & McHale 2015 p. 175.
[144] Matthews 2015 p. 499.
[145] *Id.* p. 499–502. Instead India implemented a new definition of the inventive step so that follow-on patents on pharmaceuticals would not be possible. See also Sellin 2015 p. 465–466.
[146] Matthews 2015 p. 502–505.
[147] See Minn 2018b.
[148] Matthews 2015 p. 505–507.
[149] There have also been legislative changes that have accounted for this. This development has overall increased the meaning of case law in continental Europe, because the balancing has moved from the legislative phase to courts. Also arguments regarding societal and economic effects are used more often, so in some fields court practice can be seen shifting towards a common law-like, dynamic setup. The increase in the importance of fundamental rights law is known as constitutionalization. Constitutionalization – in the meaning of rising importance of human

From these clusters the focus of this thesis is on the judicial interpretation and the courts' possibilities to change the existing balance between patents and health rights. Legislative changes are not covered by this analysis, but some of the discussed measures might also fall into the sphere of policy changes. A hypothesis of this analysis is that no legislative changes are needed to bring health rights considerations into patent law. Desired balancing methods can be adopted by interpreting existing legal sources in a new way.

3.3 Combining Health Rights and IP

3.3.1 Primacy of Health over Property

3.3.1.1 Are All Human Rights Equal?

This section is dedicated to discussing the human rights concepts that would allow health rights to have a bigger role in European patent law.[150] First, I contemplate whether health rights could be superior to property rights. The discussion here focuses on the ECHR along with the justified reasons for limiting property rights as determined by the ECtHR.

Let us first consider general conditions for limiting human rights. The ECtHR has given much consideration for balancing and proportionality. It has stated that limitation of property rights must be made by "reasonable and suited" means, but application of objectively "best" or least restrictive measures is not required.[151] This is consistent with the ECHR's nature as a provider of minimum protection. Simply the fact that more protection could have been provided does not constitute a violation of the ECHR.[152] States have the right to impose limitations on human rights in specific circumstances even if they have chosen not to or even if it is not strictly speaking necessary.[153]

Additionally, the ECtHR seems to focus almost exclusively on the legitimacy of the aims and not so much on the efficacy of the selected means for limitation. In theory, a limitation to human rights is disproportionate if it is not actually efficient at pursuing the legitimate aim in question. In practice it is understandable that the Court does not wish to engage too much in analyzing

---

rights – has been an important driver of approximation of Europe. Oker-Blom 2009 p. 188, 192–193, 195; Tuori 2018; Husa 2009; Nieminen 2010 p. 784, 786–787; Ojanen 2014.

[150] Patent law concepts are discussed in chapter 4.

[151] ECtHR case *James and Others* v. *United Kingdom* (1986) para. 51.

[152] Christoffersen 2015 p. 24.

[153] *Id.* p. 34–35.

large numbers of hypothetical scenarios, so focusing on legitimacy of aims is simpler.[154] However, this suitability test is just one aspect of the more general proportionality assessment that the ECtHR exercises.[155] What makes this assessment especially hard is the inevitable reliance on incomplete or absent empirical data on the effects of different choices.[156] Yet, exercise of proportionality does not only mean limiting rights.[157] It is inherently about balancing different interests, and in more difficult cases this balancing is based on conscious choices rather than on dictations of law.[158]

There are a few superior, non-derogable rights, these including the right to life and prohibition of torture, slavery and punishments without law.[159] The ECtHR recognizes a hierarchy within the ECHR rights e.g. by assigning priority to examination of cases where non-derogable rights are breached. Cases involving a risk for the life or health of the applicant are prioritized.[160] This implies that health is considered to be quite high in the hierarchy, even though it is strictly not the very core of the right to life. Of course, harm to health can have long-term effects on the quality of life in a different manner than interference with e.g. right to free speech.

It seems that health as a human right has to some degree primacy over property rights under the ECHR. What this means in practice is not that health interests would always prevail over property concerns, but that they must be weighed against each other appropriately when balancing them in individual cases. This conclusion has also been criticized to reflect merely an emotional hierarchy, while legal arguments would rather support the primacy of trade-related obligations governed by the WTO. This is because the WTO has enforcement mechanisms that are subject to make states behave primarily according to WTO norms. As a solution it has been suggested that human rights considerations be properly internalized into the WTO framework,

---

[154] *Id.* p. 28.
[155] *Id.* p. 29.
[156] *Id.* p. 32.
[157] *Id.* p. 33.
[158] *Id.* p. 35–36. This is frequently the case when the tension lies in the relationship of two human rights. If one of them would not be covered by the ECHR, then the ECtHR could treat it as mere interest and not an actual right, thus constructing a primacy for the ECHR rights. Recently non-ECHR rights – including especially socio-economic rights – have gained more equal treatment at the Court. But when both rights are protected by the ECHR, as is the case with IP and health rights, a hierarchy must be found within the ECHR. Ducoulombier 2015 p. 42–43.
[159] Ducoulombier 2015 p. 44. These are also known as *jus cogens*.
[160] *Id.* p. 49.

so that they would guide state behavior as equal to trade interests.[161] This notion is also relevant, but the moral superiority of health rights over property rights should also be taken seriously.

3.3.1.2 When Does Health Prevail?

Assuming that health enjoys a primacy of sorts in the human rights hierarchy compared to IP, it is logical to ask how and when such primacy would manifest in practice. There have been no big cases yet where the central issue would have been about balancing health rights and IP, but it seems that the ECtHR would probably be ready to give priority to health – at least if the health situation would be grave enough. We can imagine a case where, for example, a patentee claims violation of their property rights on the basis that the state has allowed the use of their patented pharmaceutical without permission in order to battle e.g. a spreading infectious disease. Depending on the urgency of the situation and the type of the disease, the ECtHR might say that a monetary compensation for the use has provided enough protection for the IP and that the public health interests override the patentee's right to exclude.

Considering this kind of extreme cases makes the priority of health rights seem quite clear. But the applicability of extreme cases to less dramatic scenarios is limited. Injunction is still the main rule in European pharmaceutical patent cases and health rights are not a very topical concern in these litigations. In the ECHR's practice there are also examples where a superior right did not automatically prevail over other human rights.[162] This is because the actual balancing of human rights also takes into account other factors than just theoretical supremacy. In individual cases important factors include the status of parties and the seriousness of the interference.[163]

All in all, it seems likely that the ECtHR would be willing to consider balancing IP and health rights instead of just relying on protection of property, which is directly mentioned in the ECHR documents. However, the default level of protection of IP seems to be quite strong in front of

[161] Hestermeyer 2007 p. 206–208. The authority of the WTO to apply non-WTO law, including human rights, has been extensively discussed in Hestermeyer 2007 and seems quite limited.
[162] Ducoulombier 2015 p. 50.
[163] *Id.* p. 50. The balancing situation concerned here can be compared to a situation where legislation poses limitations to how tobacco companies may present their trademarks on cigarette packages. The ECtHR would likely find it justified to limit the rights of the trademark owner based on public health interests. The court could rely on the health rights included e.g. in the ICESCR to find a positive obligation of the state to adopt means that protect the health of its citizens, even though the ICESCR is not an official part of the ECHR framework. Grosse Ruse-Khan 2015 p. 84–85.

the ECtHR. The ECtHR has had a quite positive approach to IPRs especially in cases concerning freedom of expression and copyright. Moreover, it has lots of respect for domestic balancing decisions, although it does review their proportionality especially in relation to alternative measures.[164] As the protection of IP is constantly gaining more ground on the domestic and EU level, it might be that at some point the ECtHR would be willing to put more emphasis on the realization of other human rights and thus narrow down the wide margin of appreciation.[165]

It seems unlikely that the current balance would undergo dramatic changes unless a landmark judgment would be given. The ECtHR seems like a good forum to issue one, but actually the CJEU's word might have a more direct effect on national practices. The problem with the ECtHR's judgments is that they might remain more abstract and backwards-looking and not provide so much general guidance.[166] However, thinking especially of the upcoming Unified Patent Court (UPC), it might be that the statements of both courts (ECtHR and CJEU) would be ignored as far as possible should the patent or WTO community not like them. This has been identified as a fear related to the efficacy of any interference to the practices of the UPC from non-UPC courts.[167] As a conclusion it might still be said that the most likely scenario where health rights would openly prevail over IPRs would be some kind of extreme situation. Its result might be relatively easy to bypass for general courts dealing with ordinary cases – or not, depending on the forum and the way the judgment was formulated.

3.3.2 Access to Novel Medicines as Human Right

Another human rights based way to enhance health rights in patent enforcement would be to extend the content of the right to health to more clearly also cover access to novel medicines in Europe. In practice this would mean that the concept of highest attainable level of health would be taken more literally and technically. Traditionally the starting point is that only access to essential medicines is actively protected as only access to essential medicines has been

[164] Grosse Ruse-Khan 2015 p. 86–87.
[165] *Id.* p. 88. However, the doctrine on the margin of appreciation is quite strong in cases that require contextual interpretation. The level of health protection can be included in this category. There seems to be no European consensus on the exact content of health rights and traditionally such rights have been established and interpreted on the national level. Recently the ECtHR has shown more activism in promoting certain developments. See Rautiainen 2011 p. 1154, 1157–1158.
[166] This is partly because they are sometimes bound to the legal system of the originator state. The content of a specific right as defined by the ECtHR must be read in the context of the legal system to which the interpretation was targeted. Neuvonen & Rautiainen 2015 p. 44.
[167] Dreyfuss 2015 p. 158.

mentioned by the WHO and UN organs. It is not nearly as evident that access to novel and innovative medicines would merit similar protection as a human right.

The WHO maintains statistics of the availability and prices of medicines it has listed as essential in exemplary manner.[168] The model lists of essential medicines also feature medicines more important in developed countries – that is, not only medicines against infectious diseases.[169] The concept of essential medicine is defined as medicines "that satisfy the priority health care needs of the population". They are selected "with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness".[170]

Looking at the definitions of essential medicines, it is clear that the definition of an essential medicine does not rule out the possibility that a novel medicine could also be essential. Moreover, the essential medicines of developed countries, including the EU, can be different from those of developing countries. This is important to recognize so that we can only consider health rights in the EU. This is also consistent with Article 2(1) ICESCR that calls for progressive realization of the rights of the Covenant.[171] Nowhere is it stated that access to novel medicines could not be a human right protected under highest attainable level of health. The developed countries are merely ahead some developing countries in realizing the right to health.

With this in mind, it is not unreasonable to say that the content of the right to health can be held to a higher standard in countries with more resources. In the EU for example, healthcare standards are generally high and availability of medicines is not a wide-scale issue. Thus, it might be argued that the attainable level of health includes access to a wide set of medicines, not all of which are strictly essential. Should Member States then take action to facilitate access to novel, possibly expensive treatments? In the light of the Article 168 TFEU, such decisions are part of the national healthcare policy and do not directly interfere with the right to health as

[168] WHO: Essential medicines and health products.
[169] For example, the lists include pharmaceuticals for mental diseases and contraception. The model lists are supposed to be used as models in the creation of national essential medicine lists. The model list is not supposed to be universal and applicable as such everywhere.
[170] WHO: Essential medicines and health products.
[171] The ultimate aim of this progressive realization of health rights is everyone's "complete physical, mental, and social well being" (WHO Constitution). This implies access to all necessary medicines, not just the strictly essential ones. Even if guaranteeing access to novel medicines is not currently possible, it is not permanently ruled out of the definition of health rights. See Hestermeyer 2007 p. 91.

long as healthcare is not completely denied some patients.[172] Thus, current EU legislation leaves a wide margin of appreciation for the provided level of healthcare. No EU policy actively promotes access to novel medicines,[173] so such a right remains quite weak even in the EU.

The tricky question that remains in relation to essential medicines is the exact definition of which medicines are truly essential and which are mere "convenience". Cancer is a relevant health threat in the EU – so should some novel cancer medicines be held essential? At least some novel medicines drop out of the definition of essential because of the cost-related factors. Many novel medicines are quite expensive and not that cost-effective if compared to cures for simpler diseases. This is relevant, because the resources of national health systems are limited. Putting emphasis on one expensive cure can diminish the availability of many cheaper ones and might not be socially justifiable.[174]

As a conclusion, the right to health currently does not ensure access to all necessary medicines, but only those that are essential. The definition of essential varies among countries and it is generally much broader in the EU than in many other countries. The right to access novel medicines does not exist as such, but some novel and even expensive medicines might be considered essential in some circumstances or some parts of the EU. Thus, when issuing injunctions, it should be evaluated what the status of the pharmaceutical concerned is for the affected patient populations. For example, there are regions of the EU where e.g. a hereditary disease affects a relatively high proportion of the population and poses a major public health concern in the region.[175] For this subpopulation in the EU, the pharmaceutical might be essential. If this is the case, then the realization of health rights should be considered in determining whether and what kind of injunction should be granted. In situations like this it would seem tempting not to issue an injunction at least to the part of the EU where its health effects would be most negative. From these examples we move to consider injunctions more concretely and from the perspective of patent law.

---

[172] However, it can be questioned whether the endeavor to reduce public spending on healthcare is consistent with the duty to ensure high level of health protection. Tuominen 2012 p. 542.
[173] Unless adaptive pathways count as such.
[174] Carbone 2003 p. 214. There are also significantly more uncertainties and risks related to novel treatments, so social justice might also require that emphasis is put on the safest options.
[175] Jelf 2017 p. 12.

4. Judicial Discretion in Granting Injunctions

4.1 The May or Shall Problem

After considering the more theoretical aspects of the research question, this chapter will take a concrete approach and consider injunctions specifically. Injunctions are the ultimate embodiment of the right to exclude. With an enforceable injunction the patentee can physically prevent the sale or import of infringing products. It is a powerful tool for the patentee. Its use can also have visible effects on the society by making an infringing product unavailable for consumers. Taking into account its significance, it is understandable that stakeholders and scholars have given much thought for whether injunctions should always be issued or not. There are arguments for both sides.

The debate first culminates into the question of whether courts have discretion under current legislation not to grant an injunction after an infringement has been established. This is what I refer to as the may or shall problem. Typically, the provisions granting courts the power to issue injunctions use the wording "the court *may* grant an injunction". This is frequently interpreted as "the court *shall* grant an injunction". The first part of the issue is thus the legal dogmatic question of how the legal provisions should be interpreted taking into account the patentee's right to exclude and factors that may sometimes speak against the exercise of that right. Is the grant of an injunction supposed to be automatic is discretionary?[176] This question and the content of what I call a traditional approach will be addressed in the following sections.

The second part of the problem is the question whether discretion should exist and whether it should be exercised – and on what basis. It is possible to argue that the lenient formulation of the provisions should be put to use more often. Usually such cases would be those where a public interest is involved, for example competition or public health. The exact balance of different interests in the exercise of the discretion is tough to strike and cannot be unequivocally set in the legislation. Sometimes there are no other compelling interests involved and the patentee's right to exclude can be exercised without further considerations. Sometimes

[176] I.e., Must the court always grant an injunction after infringement has been established or does can it weigh and balance different interests at this stage?

exclusivity may seem secondary in the bigger picture. The discussion of these issues will be started in this chapter and continued in chapter 5.

4.2 Traditional Approach to Injunctions

4.2.1 Right to Exclude in the Light of the Enforcement Directive

There is no official unified approach to injunctions in Europe, although a common base for enforcement measures in the EU has been reached by the Enforcement Directive (Directive 2004/48/EC). According to Article 3(1) of the Directive, the enforcement "measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays". Moreover, Article 3(2) requires that the "measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse". Hence, the Directive seems to contain the idea of balancing different societal interests in the application of the enforcement measures.

Article 11 concerns injunctions and states that "Member States shall ensure that, where a judicial decision is taken finding an infringement of an intellectual property right, the judicial authorities may issue against the infringer an injunction aimed at prohibiting the continuation of the infringement". Despite this statement that courts "may issue -- an injunction", no conclusions can be drawn from this provision on the actual discretion of European courts in granting injunctions. This is because the articles of the Directive are directed at the law maker, who must then draft the national law to be compliant with the Directive. Thus, what the provision actually means is merely that courts "shall have authority" to issue injunctions.[177]

Another feature of the Directive worth mentioning here is Article 12. Its implementation was voluntary and not many countries have included it in their national patent laws. It contains a proportionality exception that only applies to a very narrow set of circumstances.[178] Article 3 – titled "General obligation" and quoted above – includes the general and primary requirements that all provided measures must satisfy independent of whether the national law makes use of

[177] Marfe et al. 2015 p. 181, 188. This is consistent with the Directive's purpose of minimum harmonization. See Norrgård 2005 p. 506.

[178] These circumstances include unintentional and non-negligent infringement, and that the standard measures would be disproportionate, and that pecuniary compensation is reasonably satisfactory. Especially the first requirement would rarely apply to (pharmaceutical) patent cases, because the infringer is normally assumed to be aware of the relevant patents in their field of technology.

the narrower exception of Article 12. Direct application of Article 3 might act as a basis for discretion in the grant of injunctions, although in some cases it might activate the problem of Directives' horizontal effects and thus might not be a good basis for radical changes on the national level.[179]

Article 3(2) of the Enforcement Directive specifically allows for discretion of sorts, namely the requirement of propo**r**tionality of available means. In practice national courts tend to treat the rights conferred by a patent as an obligation to issue an injunction if requested. Proportionality does not even arise in the discussion, because it is thought to be incorporated into the legislation. Even the infringers rarely argue that the grant of an injunction would be disproportionate or otherwise contrary to public interest.[180] This probably speaks for a practice so established that it is not considered fruitful to question. Furthermore, Article 3 also calls for effective and dissuasive means and does not specify how these aims should be combined with proportionality. Thus, no general guidelines for discretion can be drawn from the Article or the Directive.[181] At least the current practices are not contrary to the Directive, because the Directive is so ambiguous in these respects, but different interpretations could also be justified.

Article 3 also prohibits abuse of rights and barriers of trade. They could sometimes be used as arguments against or in favor of injunctions. None of the countries studied by Marfe et al. – Germany, France, Italy and Netherlands – has in their patent law any general proportionality requirements nor are there any obvious legal ways to apply such a criterion under national law.[182] From the "constraints" of Article 3, only the abuse and trade barrier conditions are clearly applicable in national courts, the former through general principles and the latter through competition and internal market law.[183] This might explain why the balancing discussion concerning injunctions has been so limited in Europe.

---

[179] Directives can sometimes have horizontal effects i.e., effects between two private parties, but as main rule they will only bind states in their legislative actions. In this case it might also be questionable whether the proportionality requirement would qualify as a right conferred to a private party, because it clearly reads more as a general guidance to the legislator. Of course, this issue will not arise if a similar provision has been implemented in the national law, but not nearly all countries have such provisions. Thus, it might be hard for a national court to base a new discretionary approach solely on Article 3. See Raitio 2013 p. 357–360.
[180] Bennet – Roux-Vaillard – Mammen 2015 p. 24.
[181] Marfe et al. 2015 p. 181.
[182] *Id.* p. 189.
[183] *Id.* p. 181. Implications for internal market have been an important argument in discussions concerning unitary and Europeanized IP rights. See Smits & Bull 2013 p. 42.

Germany, France, Italy and Netherlands all have a strong disposition in granting injunctions under their patent laws. Only in exceptional circumstances have other concerns prevailed – for example, if an application for injunction has been made during FRAND license negotiations.[184] All of these countries also evaluated themselves to be compliant with the Enforcement Directive without major changes to their national patent laws. Similar practices and implementation histories are found throughout the EU.[185] Thus, the current practices in Europe are in no way a result of the Directive. They are part of a much longer tradition and an expression of the property rule's effect. According to Norrgård,[186] this effect is mirrored in the Directive in the emphasis it puts on "high" level of IP protection. Nevertheless, on the level of individual Articles the Directive seems to leave a lot discretion for the national judge. Thus, there are no definitive rules on either EU or national level, but in practice the right to exclude remains quite absolute.

4.2.2 Traditional Approach in the USA

The starting point has been quite similar in the USA as in Europe. This was the case especially before the landmark case *eBay* in 2006. The US Patent Act recognizes the right to exclude as a right of the patent owner (35 U.S.C. § 154(a)(1)). The authority to grant injunctions is based on 35 U.S.C. § 283 that reads: "courts -- may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable".

The injunction provision is as such formulated in a more discretionary way that the corresponding European provisions. However, it used to be interpreted according to the "shall" doctrine, meaning that an injunction was a more or less automatic consequence of an established patent infringement.[187] The "right to exclude" had been specifically recognized in a Supreme Court case in the 1850s and further expanded to non-practicing patentees in the early 1900s.[188]

---

[184] Marfe et al. 2015 p. 181–184.
[185] For example, the Finnish Supreme Court has stated in a 2003 case that the starting point in patent infringements is that an injunction is ordered if the patentee claims it. Only in cases where there is no threat of recurring or continuing infringement could a court deny the claim for an injunction. The Court also referred to the possibility to obtain a compulsory license in case a substantial public interest was involved. This remains the legal state. Despite this strong disposition for injunctions, their practical significance has sometimes been questioned in Finnish jurisprudence because of the long time from the observation of an infringement to the grant of an injunction. This perspective has increased the (at least theoretical) significance of preliminary injunctions. See case KKO:2003:127 and Norrgård 2004 p. 1064.
[186] Norrgård 2005.
[187] Bennet – Roux-Vaillard – Mammen 2015 p. 24.
[188] Seaman 2016 p. 1960.

General common law principles provided little if any equitable discretion.[189] The human right status of the right to exclude and the indistinguishability of physical and intellectual property had also been recognized in court practice.[190] Hence, injunctions used to be the standard remedy for patent infringement.[191]

In the USA, patent litigation happens mainly in federal district courts, where the court of appeals is the Federal Circuit.[192] When the Federal Circuit was established in 1982, the practice of granting permanent injunctions became governed under the precedents of this new court of appeals.[193] Under the Federal Circuit, it became a firm rule that "an injunction should issue once infringement has been established unless there is a sufficient reason for denying it".[194] Such sufficient reasons were rarely at hand.[195] In practice injunctive relief could only be denied in very rare instances where public interests were compromised because a patentee would not practice the invention.[196] The basic presumption used to be that a recurring infringement would cause irreparable harm to the patentee and thus injunctions should be issued.[197]

The appropriateness of patent remedies has been a much hotter topic in the USA than in the EU, generally due to the bigger volume and some peculiarities of the system that together allow a larger diversity of high-profile cases to arise. Before *eBay*, it was widely accepted that the issuance of injunctions was justified and belonged to the essence of patent rights.[198] Of course,

---

[189] Riley & Allen 2015 p. 755.
[190] See *Panduit Corp.* v. *Stahlin Bros. Fibre Works* (1978) footnote 5: "Patents must by law be given 'the attributes of personal property.' 35 U.S.C. § 261. The right to exclude others is the essence of the human right called 'property.' The right to exclude others from free use of an invention protected by a valid patent does not differ from the right to exclude others from free use of one's automobile, crops, or other items of personal property. Every human right, including that in an invention, is subject to challenge under appropriate circumstances. That one human property right may be challenged by trespass, another by theft, and another by infringement, does not affect the fundamental indicium of all 'property,' i.e., the right to exclude others."
[191] Golden 2010 p. 514. As a comparison, preliminary injunctions have been used quite rarely.
[192] Another forum for patent disputes is the International Trade Commission (ITC), which is an independent quasi-judicial agency dealing with importation matters. The ITC has the authority to issue exclusion orders, which are injunction-like instruments applying to importation. Historically neither the ITC nor the district courts have put much consideration into the public interests surrounding a patent infringement dispute, although the ITC has been better equipped to do so, since it has mandate to take into account public interest arguments. For the federal courts, possible public interest considerations have stemmed only from general common law, the position of which has been rather weak in these matters. See Riley & Allen 2015 p. 755. Sometimes patents can also be litigated in state courts, but this is exceptional.
[193] Riley & Allen 2015 p. 755.
[194] 842 F.2d 1275 *W.I. Gore* & *Associates v. Garlock* (1988).
[195] Seaman 2016 p. 1961–1962.
[196] Riley & Allen 2015 p. 756.
[197] *Ibid*.
[198] Merges & Duffy 2011 p. 941–942.

many still support this interpretation. There are several reasons to why this rule was replaced. In the USA, the economic arguments related to patent infringement have received a lot of attention compared to the more rights-based approach in Europe.[199] A general aim of patent remedies is to encourage desirable behavior[200] and otherwise allow the market to function normally.[201] This perspective explains where the increasing criticism of the injunction-based remedy system might have come from. Especially the emergence of so-called patent trolling[202] encouraged questioning the justification of injunctions. It raised to wider awareness the notion that any system with absolute rules is likely to give unsatisfying outcomes in a significant portion of cases and thus discretionary legal rules should be favored.[203] Many scholars have identified additional circumstances that support the idea that the special position of injunctions might not be so well-founded and the option to use other remedies better ensures the pursuit of common goals.[204]

Overall, the injunction principles of the USA used to be quite similar to the EU. Since *eBay* in 2006 the situation has changed a lot, as will be discussed in detail in the following sections, and discretion has become the new norm. As mentioned above, the US injunction clause is much more pointedly discretion-friendly than the European counterparts, reflecting the underlying common law traditions. Thus, it was not totally unexpected that the USA would choose to activate the full meaning of the provision. Its effects will be analyzed below, but before that discretionary systems will be discussed in a general manner.

---

[199] Golden 2010 p. 524.
[200] This includes behavior on both the patentee's and the potential infringer's side, for example on one hand development of new patentable technologies and on the other hand development of non-infringing alternatives.
[201] Golden 2010 p. 509–511.
[202] This refers to claims of compensation for patent infringement by non-practicing entities (NPEs) backed up by the threat of an injunction. Typically, the patent behind the claims might be rather weak, but many corporations still choose to pay the fees under the threat of a litigation. This has been developed into a controversial business model known as patent trolling, which has increased patent-critical voices in the public. Not all NPEs in the licensing business can necessarily be viewed as patent trolls. Patent trolling has not been much of an issue in Europe, but it is a widely recognized phenomenon in the USA.
[203] Golden 2010 p. 553.
[204] See Sichelman 2014. Sichelman, for example, argues that patent remedies should always focus on maximizing incentives to innovate rather than compensating the "wrongs" suffered by the patentee.

4.3 Rise of Balancing Requirements

4.3.1 Why Introduce Discretion?

This section 4.3 will contemplate the reasons why a discretionary approach to injunctions might be desirable and what has made it rise to such a hot topic. The right to exclude still enjoys a fundamental position in patent law, but the grant of injunctions has invoked lots of discussion in several jurisdictions. The big debate is about whether the right to exclude conquers all other interests at stake in a patent litigation or whether there should be equitable discretion.

European courts have typically not paid much attention to the question whether injunctions should be granted to patentees who have succeeded at an infringement trial. Injunctions have been granted automatically in both continental Europe and the common law systems, although the historical basis has been somewhat different.[205] Whether the automatic grant of injunctions is indeed proportional has not yet been thoroughly tested in the EU.[206] As noted above, the protection of property has become wider as its human rights status has been confirmed. Yet, it can be limited just like other human rights in case a public interest demands it or it must be balanced with another human right.[207]

The logic behind being very lenient in granting injunctions has been put to words by Klar as follows: "Courts' preference to grant permanent injunctive relief in patent law suits stems from a belief that once infringement has been established denying a patentee the right to exclude others is contrary to the laws of property".[208] There are also voices critical of this approach that argue that the nature of patents as property does not require that the right to exclude is so strong. The incentive to innovate need not suffer if injunctions are replaced by monetary damages. Moreover, it would not inevitably produce huge amounts of uncontrollable infringement, if the monetary damages are properly sized and readily available.[209]

According to some, the issue should be referred to the CJEU in Europe,[210] although many patent experts are generally unhappy with how the CJEU has dealt with IPRs in the past.[211] This general

[205] Bennet – Roux-Vaillard – Mammen 2015 p. 22.
[206] *Id.* p. 23.
[207] Hestermeyer 2007 p. 152.
[208] Klar 2006 p. 855.
[209] Ayres & Klemperer 1999 p. 988.
[210] Bennet – Roux-Vaillard – Mammen 2015 p. 23.
[211] Pila 2015 p. 20.

distrust in the CJEU's logic is one of the main reasons why the role of the CJEU was minimized within the UPC framework.[212] It is particularly the CJEU's rising concern for human rights that has not inspired confidence in patent experts.[213] Yet, patent law cannot exist in isolation of the surrounding society and the CJEU might actually be more competent in taking into account all the competing interests than a specialized patent court.[214] This is why it might be good if the CJEU provided some guidelines for the exercise of discretion – should the discretionary trend develop a substantial role in European patent law.

Especially in the case of pharmaceuticals it could be the human rights concerns that could justify the exercise of discretion and possible denial of injunctive relief. As mentioned above, the CJEU has become more willing to entertain such arguments and involve human rights rhetoric into its judgments. It would be important that the relevant rights are interpreted correctly and consistently. The situation is comparable to the use of moral arguments against patent grant: if an incompetent forum (i.e., a patent authority) is forced to make extensive judgments of what is "desirable", the balance is in danger of becoming distorted.[215] Similarly, the balance between patent protection (including the right to exclude) and health rights should not be left solely for specialized patent courts to address, because it is a value-based assessment affecting the entire society.

Making the right to exclude weaker and subject to a court's discretion would force pharmaceutical companies to change strategies and rethink their business models to stay profitable. This might not necessarily be a bad thing, but it is clearly not in the interest of innovative pharmaceutical companies. Where the balance is struck and how far the innovators need to compromise will be a key question for future pharmaceutical business.

4.3.2 The Case of SEPs and Needs for Balancing

During the last couple of decades the general trend has been that the right to exclude has become less and less absolute. Like many legal movements, this has first arisen in the USA. The court practice underwent a radical shift with the *eBay* judgment of the US Supreme Court,[216] and it

[212] *Ibid.*
[213] E.g. criticism of the case C-34/10 *Oliver Brüstle* v. *Greenpeace*. See Pila 2015 p. 20.
[214] Pila 2015 p. 21.
[215] Enerson 2004 p. 720.
[216] 547 U.S. 388 *eBay* v. *MercExchange* (2006).

will be extensively discussed in the following sections. The discretion discussion is still blooming. In Europe, similar conversation has started on a more general level now that the coming of the UPC provides an opportunity to scrutinize existing practices. So far the discussion has been mostly limited to competition-related public interests that are the most prevalent in the context of standard essential patents (SEPs). In the context of pharmaceuticals the discretion rhetoric remains quite rare, although, as demonstrated in this thesis, there are valid reasons to why it might be involved more.

While approaching the topic of discretion on a more general level, I will briefly describe the most relevant points of the SEP discussion to have an image of the dynamics of a sensitive balance. The discussion about whether discretion should exist and be exercised has arisen most of all in the context of mobile phones and similar multi-function devices.[217] The defendants of these litigations have argued that it is unreasonable that a single patentee could force the entire product out of the market, when the product utilizes hundreds of patents and parts.[218] These devices typically make use of SEPs, which represent technology that has been set as a standard for a specific solution. Compliance with the standard is in practice mandatory inter alia because consumers discriminate against non-compliant products.[219] This is why standard setting organizations require that SEP owners commit to license on so-called FRAND conditions (fair, reasonable and non-discriminatory). This is supposed to promote sharing of standardized technology and to minimize the drawbacks of extensive patenting.[220]

There are two classical settings that are detrimental to the market and public interest, but can result in if patent business does not operate smoothly. The first is called hold-up and it refers to a situation where the patentee uses the threat of an injunction to pressurize licensees to pay unreasonably high fees. The second is known as hold-out and it means a situation where someone uses a patented technology without paying for a license.[221] The availability of injunctions has a huge effect on the usability of these strategies. If injunctions are readily available for all patent owners, the hold-up problem becomes more imminent. Similarly, if they

[217] Bennet – Roux-Vaillard – Mammen 2015 p. 22.
[218] *Ibid.* This is obviously not the case for pharmaceuticals.
[219] Picht 2016 p. 365. There is also a public interest for interoperability, to which compliance with standards contributes.
[220] *Ibid.* The competition law aspects and dynamics of FRAND have been discussed a lot in literature, see e.g. Torti 2012.
[221] Picht 2016 p. 365–366, Torti 2012 p. 388–389.

are available only in very rare and specific circumstances, hold-out is more likely since patent owners lack effective means to prevent infringement. These issues have been widely discussed in the context of SEP licensing, because lots of disputes arise from these settings.[222] The arguments made about how available injunctions should be has also general relevance for the may or shall debate and the relationship of the property and liability rules.

4.3.3 Controlling the Availability of Injunctions

The issues highlighted with the SEP cases reflect the need to consciously control the availability of injunctions. Even though the right to exclude has typically been very strong, these disputes have raised to awareness the idea that granting an injunction might sometimes be so much contrary to public interest that the interests of the patent owner could be overridden. This is what the discretionary approach would ultimately be about: looking at the specific circumstances of each case and finding a balance between different interests.[223]

The CJEU has addressed this issue in the context of SEPs in the landmark case *Huawei* v. *ZTE*, where it set behavioral requirements for both parties of a SEP dispute.[224] If these requirements are not met, there might be a legitimate reason for an infringement suit or an abuse of a dominant position procedure, depending on the party. The balance struck by the CJEU has been further refined especially in German court practice.[225] Overall, many are of the opinion that applying for an injunction is generally not compliant with FRAND obligations.[226] This is why some standard setting organizations' rules specifically forbid seeking injunctive relief.[227] This is considered a powerful way to prevent hold-up and instead promote damages as an enforcement tool.[228] It seems that the liability rule is prevailing in the SEP context also in the EU.

The use of injunctions by SEP holders has been limited both in the EU and in the USA.[229] Otherwise there are still significant differences in the general approach to injunctions. The reasons used for limiting SEP injunctions worldwide include principles of equity, public policy,

---

[222] Picht 2016 p. 366.
[223] Although in US literature the focus is sometimes rather on preventing overcompensation to patentees. See e.g. Lee & Melamed 2016 p. 433–437.
[224] C-170/13 *Huawei Technologies Co. Ltd*. v. *ZTE Corp*. (2015).
[225] Picht 2016 p. 369–370.
[226] Nicolic 2017 p. 127.
[227] *Ibid.*
[228] *Ibid.*
[229] *Id.* p. 128.

unfair competition, competition law and abuse of rights.[230] So far only the competition law argument has been employed by the CJEU, although a few European courts have also invoked abuse of rights.[231] It has been suggested that interim payments should be favored in SEP cases to avoid the drawbacks of injunctions and to discourage hold-out strategies.[232]

Applicability of the SEP arguments to pharmaceutical patents is limited, because pharmaceutical companies make no commitment of licensing.[233] The infringer cannot thus argue to have any kind of subjective "right" to use the invention.[234] No similar abuse claims can be made of pharmaceutical patent enforcement as long as there is no dishonesty involved. A direct analogy thus fails, so the possible existence of discretion must be constructed on other arguments. To answer the question about pharmaceutical-specific European discretion, I will use the US practice as a springboard to understanding what kind of discretion might be introduced into the legal system and how it could be applied in practice. Further below, these perspectives will be applied to the European discussion.

4.4 Wide Discretion and eBay Criteria

4.4.1 Effects of *eBay* v. *MercExchange* on Patent Litigation

In 2006, the US Supreme Court gave a judgment in the matter *eBay* v. *MercExchange*.[235] In the judgment, the Court fundamentally changed the established case law for granting injunctions. Instead of them being issued automatically, the Supreme Court extended the traditional four-factor test to apply to permanent injunctions. In practice this meant that patentees could no longer rely on injunctions being issued as a matter of course, but that they have to provide evidence that such a remedy is indeed necessary. Before *eBay* the test had only been used in the context of preliminary injunctions.[236]

---

[230] *Ibid.*
[231] *Id.* p. 131–132.
[232] *Id.* p. 135.
[233] Slowinski 2018 p. 129.
[234] This is all the more true because in the case of pharmaceuticals the infringing part is typically the entire product, not just a tiny piece of it.
[235] 547 U.S. 388 *eBay* v. *MercExchange* (2006)
[236] Allen 2013 p. 1053–1054; Norrgård 2002 p. 160. European courts, too, exercise discretion in the grant of preliminary injunctions, but there has typically been no equally sophisticated tests to set the threshold to when they should be issued. See Norrgård 2002.

The four-factor test is a general test applied for the equitable grant of any kind of injunction.[237] According to the test, an injunction should only be issued, if the plaintiff demonstrates "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction".[238] As a result of *eBay*, this test is now used for permanent patent injunctions, too.[239]

The *eBay* case has been vigorously discussed in academia and the criteria are applied by lower courts frequently in injunction cases. However, according to empirical studies, most infringement cases still end with the grant of a permanent injunction, the overall injunction rate post-*eBay* being somewhere between 70–80 %.[240] This rate used to be close to 100 % pre-*eBay*, but has since slowly dropped to just below 70 %.[241] However, there are significant differences in the statistics of different courts, their injunction grant rates varying between 50–92 %. Part of these differences is explained by the type of cases these jurisdictions deal with.[242]

There are major differences in grant rates depending on industry. Pharmaceutical cases nearly always result in an injunction while computer software cases rarely do.[243] In the decade following *eBay*, the injunction grant rate was the highest for biotechnology (100 %) and pharmaceutical (92 %) patents.[244] As a comparison, the grant rate for medical devices was only 65 %, which is interesting, because they are also susceptible to similar public health interests as

---

[237] 547 U.S. 388 *eBay* v. *MercExchange* (2006) holding.
[238] *Ibid.*
[239] The other patent tribunal of the US – the International Trade Commission (ITC) – is not formally bound by the *eBay* ruling, so its issues with discretion resemble more those of the EU. According to the Tariff Act governing the ITC, infringing goods shall "be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare -- [the ICT] finds that such articles should not be excluded from entry" (19 U.S.C. § 1337(d)(1)). This section shows that the ITC – mainly dealing with import issues – is at least theoretically well-equipped to take into account public interests in its decisions, also public health. Such interests could in individual situations override the patentee's right to exclude infringing goods from the market. Then again, an exclusion order is the only remedy available from the ITC, so the agency starts from a very clear standpoint that all infringing goods are to be excluded from importation. This might explain why the exception provision is quite strong, although it has rarely been applied. See Nicolic 2017 p. 129–130; Riley & Allen 2015 p. 758–765; ITC Investigation No. 337-TA-543 p. 156.
[240] Seaman 2016 p. 1969.
[241] *Id.* p. 1983–1984.
[242] *Id.* p. 1987.
[243] *Id.* p. 1953.
[244] *Id.* p. 1985.

pharmaceuticals. One explanation for this difference is the different standards applied by lower courts to these categories. Patents are – and are recognized to be – vital for pharmaceutical and biotechnology industries because of the high R&D costs, so they are also more often perceived to be genuinely in need of injunctive relief.[245] Medical devices are in this respect closer to SEPs.[246]

Also the relationship of the companies involved is a statistically significant factor. Injunctions are likely to be issued in disputes between competitors (84 % grant rate) and less likely if the companies are not in direct competition (21 %).[247] In typical pharmaceutical cases the parties would be competitors (i.e., originator and generic company) and this probably also contributes to the high injunction grant rate of pharmaceuticals. However, for medical devices the grant rate is low also between competitors precisely due to public health interests, like in the case of *Johnson & Johnson Vision Care*.[248]

Licensing activities of the patentee may also affect whether an injunction is granted, although studies show that even if the patent had been licensed to others, injunctions were issued in most cases.[249] In a classical pharmaceutical setting the patent would not have been licensed to others, but used exclusively by the patentee. This generally speaks for the grant of injunctions. Also when the patent only covers a small component of the end product it is unlikely that an injunction is deemed appropriate.[250] Traditional blockbuster medicine patents cover basically the entire product, so the small component objection would typically not apply. Also whether the infringement was willful has been raised as a factor speaking for the grant of an injunction, but there is no empirical evidence of this having an effect on the outcome.[251]

According to this statistical analysis, pharmaceutical patents still enjoy a strong position in the US injunction market. In the following section, the interpretation of the *eBay* criteria in medical context will be discussed in more detail. Special consideration will be given to the requirements

---

[245] *Id.* p. 2005.
[246] And some of them might actually incorporate SEPs. Thus, a part of the low injunction grant rate might be explained by the fact that SEP case-like argumentation was involved instead or on top of public health arguments.
[247] Seaman 2016 p. 1990. In the early years post-*eBay* a lot of emphasis was put on this factor by district courts. See Diessel 2007 p. 344.
[248] Seaman 2016 p. 1991. In *Johnson & Johnson Vision Care* v. *Cibe Vision Corp*. (2010) patients' interests to keep using their trusted, infringing contact lenses prevailed over the patentee's right to exclude.
[249] *Id.* p. 1971.
[250] *Id.* p. 1972.
[251] *Ibid*.

of irreparable harm and not disserving the public interest.[252] Later on, these interpretations will be analyzed from the European perspective.

4.4.2 Application of *eBay* Criteria on Pharmaceutical Patents

4.4.2.1 Irreparable Harm and Interests of the Patentee

The *eBay* criteria require that irreparable harm has occurred to the patentee. This criterion has been held problematic from the perspective of the owner of a pharmaceutical patent. This is because patent infringements generally result in economic harm, but such harm can rarely be considered irreparable.[253] Thus, a very strict interpretation of this criterion does not support an exclusivity-based business model or a strong right to exclude. Pharmaceutical patent infringements regularly result in loss of goodwill and pricing power. These are hard to estimate in monetary terms, so these features might not be adequately compensated, if an injunction were denied.[254] On this basis, it has been recommended that the evaluation of irreparable harm should more concretely focus on the loss of exclusivity and harm resulting from that instead of factual monetary losses.[255]

In practice, US courts seem to interpret this criterion in a rather broad manner that does not discriminate against pharmaceutical companies. The types of irreparable harm that have been accepted by US district courts include loss of market share, loss of goodwill, loss of business opportunities, price erosion and inability of infringer to pay monetary damages, the most common by far being the loss of market share.[256] In the scenario where a generic pharmaceutical has entered the market, the types of harm applicable would typically include at least loss of market share and price erosion.[257] Since the occurrence of these incidents at market entry of generics is a truth universally acknowledged, an innovative pharmaceutical company would usually fulfil the irreparable harm criterion.

---

[252] Only these two criteria will be extensively discussed, because the inadequacy of other remedies and the balance of hardships seem to fuse into the criterion of irreparable harm. For this analysis the public interest factor is especially interesting, but irreparable harm will also be considered to get a more complete picture of the competing interests.
[253] Jacobs & Zhang 2013 p. 36; Norrgård 2002 p. 163.
[254] Jacobs & Zhang 2013 p. 36.
[255] *Ibid.*
[256] Seaman 2016 p. 1993.
[257] Song & Han 2016 p. 4. Price erosion refers to the permanent pressure to stay the lower prices. It is often impossible to regain the lost market share and reset the prices to their initial level once generic products have been on the market.

Also speaking for irreparable harm is the fact that the future innovation activity of the pharmaceutical company depends on its ability to recoup its investments with its successful products. If the cash flow is disrupted, it could have long-term effects on the company's viability.[258] The absence of other adequate remedies also overlaps significantly with the harm criterion and there is a huge correlation in the conclusions concerning these two criteria in US court interpretations.[259]

There have been cases in the US where the grant of an injunction for a pharmaceutical company has been assessed on the *eBay* criteria. As could be assumed, irreparable harm has been established based especially on loss of market share, price erosion and loss of goodwill. Courts have also recognized the threat that infringement will continue and cause even more large and unquantifiable harm, if no injunction is issued. In pharmaceutical cases injunctions have been granted, when the patentee has successfully delivered these arguments of irreparable harm and insufficiency of monetary compensation.[260] As seen above, the grant rate has remained high.

It can still be concerning for companies that an injunction could be denied if the patentee for some reason fails to substantiate these claims. There has been at least one case,[261] where the district court denied injunction on the basis that evidence on prospective irreparable harm was inadequate. It argued that all past harms could be compensated by damages, and only prospective harms could support the claim for injunction.[262] In the said case, the Federal Circuit ended up criticizing this approach and stating that *eBay* does not mean that there would be "a presumption against exclusivity on successful infringement litigation".[263] The right to exclude still exists, but there is also equitable discretion. In their exercise of the discretion, courts should take into account the exclusivity-related losses that have resulted from the infringement.[264]

What also speaks for finding of irreparable harm is the holding of exclusive market before infringement took place. In such a setting it is easier to show that the growing sales of the infringer have happened directly to the detriment of the patentee. On the other hand, if the patent

---

[258] Stiefel & Carter 2016 p. 2.
[259] Seaman 2016 p. 1994. This is why it is not discussed separately. The balance of hardships also does not have independent meaning in this analysis, so it is not discussed.
[260] Stiefel & Carter 2016 p. 2.
[261] 699 F.3d 1305, 1314 *Edwards Lifesciences* v. *CoreValve* (2012).
[262] Stiefel & Carter 2016 p. 3.
[263] 699 F.3d 1305, 1314 *Edwards Lifesciences* v. *CoreValve* (2012).
[264] Jacobs & Zhang 2013 p. 37.

has been licensed it can be hard to show that there would be irreparable harm that could not be compensated by damages.[265] Such a comment was also made in the *Johnson & Johnson Vision Care* case,[266] where licenses had been offered to competitors. This was in contradiction with a very strong interest in exercising the right to exclude. Still, it has not been ruled out that the emergence of a new infringing market player could cause irreparable harm even when there already are multiple companies offering the same product.[267]

Overall, it must be concluded that the irreparable harm criterion generally supports the injunction claims of pharmaceutical companies. It seems to quite smoothly allow the courts to consider the interests of the patentee. However, there remains some insecurity that contributes to the general inconvenience of the test for patentees – after all, the other *eBay* criteria might not be fulfilled. That an injunction must "not disserve public interest" is a particularly interesting test from the perspective of health rights. It will be analyzed next.

4.4.2.2 Not Disserving Public Interest

The *eBay* criteria only require that the injunction is not contrary to public interest – not that it would necessarily promote public interest.[268] In the context of pharmaceuticals it should be noted that the public interest of benefiting from access to lower priced medicines cannot as such be held to override the public interest of encouraging investments in risky pharmaceutical development.[269] There can also be a public interest into the numerous jobs provided by the patentee, so the criterion does not only work in favor of the infringer.[270]

The public interest criterion of *eBay* seems to have a lot of weight over whether an injunction is deemed appropriate in practice, and it might even be decisive.[271] At the time when eBay was issued, patent owners worried that compulsory licenses would be issued to any competitor that mentioned this argument.[272] During the first decade post-*eBay*, US district courts have addressed

---

[265] Stiefel & Carter 2016 p. 3.
[266] 712 F.Supp.2d 1285 *Johnson & Johnson Vision Care* v. *Cibe Vision Corp.* (2010).
[267] Stiefel & Carter 2016 p. 3.
[268] This is the official formulation, although Kennedy, J., did in their concurring opinion argue that the grant of injunctions for infringements concerning small components of complex products "may not serve the public interest" – thus turning the criterion upside down. There is no statutory rule for taking into account public interest.
[269] Stiefel & Carter 2016 p. 4.
[270] Merges & Duffy 2011 p. 949.
[271] Seaman 2016 p. 1995.
[272] Klar 2006 p. 585.

public interest in permanent injunction cases at least fifteen times.[273] In these cases, public interest has been quite narrowly interpreted to mean concerns related to public health, public welfare and public safety.[274] In practice it seems that discretion is regularly exercised only in matters that involve "sickness, injury or medicine", and this tendency is self-feeding because of precedent mechanisms.[275] It has even been suggested that it would be a successful litigation strategy for avoiding injunctions to tie the product – even loosely – to protection of health. Health-related claims of public interest seem to merit more attention and sympathy than others in US district court practice.[276]

As to the substantial criteria for refusal of injunction – i.e., situations when the public interest prevails – it is possible to identify at least one case type. That is a situation where the injunction would make a socially valuable product completely unavailable.[277] This could be the case when there are no lawful versions of the infringing product available, e.g. when the patentee does not manufacture a similar product. This is not the typical way we perceive pharmaceutical patent infringement – rather the products tend to be entirely substitutable. Sometimes it is possible that the infringer's product is slightly different in ways that make it safer or otherwise better suitable for some patients or applications.[278] In these situations public interest might support denial of an injunction.

For example in the *Johnson & Johnson Vision Care*[279] case, an injunction was denied based on public health interests. The underlining interest was the interest of contact lens users to continue using their preferred type of lenses that allegedly possessed specific medical advantages. Another argument was that doctors should be free to determine which type of vision correction method best suited each patient. The court found these arguments persuasive and put emphasis on the prospect of "innocent" contact lens users facing confusion and additional costs as well as on concerns regarding the availability of proper vision care. Some scholars have expressed surprise for the outcome taking into account the lack of scientific evidence and the multiplicity

[273] Riley & Allen 2015 p. 765.
[274] *Id.* p. 766.
[275] *Id.* p. 767.
[276] *Id.* p. 775.
[277] *Id.* p. 768.
[278] Stiefel & Carter 2016 p. 4. This is more common in the case of medical devices that obviously have more possible ways to construct a functioning product.
[279] 712 F.Supp.2d 1285 *Johnson & Johnson Vision Care* v. *Cibe Vision Corp.* (2010).

of alternatives for affected users. According to them, the case manifests an expansion of the concept of public interest in district court practice.[280]

Although the case was not about pharmaceuticals, it exhibits the core arguments that can be made in favor of denying injunctions based on health. A curious aspect is the meaning of the inconvenience of users, when there are no vital interests involved. According to Riley and Allen, "when technology becomes so fundamental to everyday existence, the public necessity for any one particular invention may start to mimic the traits of life-saving technology"[281]. If this is true, then the "popularity" of a product could play a major role in determining whether an injunction is appropriate from the point of view of public interest.[282]

Such features can be observed in the reasoning of *Johnson & Johnson Vision Care*, because the large number of users and doctors preferring the infringing product seemed to weigh a lot in the court's reasoning. There have also been unofficial court opinions suggesting that the existence of options is as such a public interest and an infringing product need not demonstrate specific advantages to avoid injunction.[283] This was the conclusion of the District Court in the case *Amgen* v. *Sanofi*.[284]

Yet, if there are alternatives available, the fact that patients need to change to a non-infringing product cannot significantly disserve the public interest. This has been the holding in many medical devices cases.[285] The argument is also supported by the Federal Circuit's judgment in *Amgen* v. *Sanofi*.[286] The Federal Circuit stated that the District Court had erred in its analysis of the public interest factor when granting an injunction for a pharmaceutical patent. The District Court had concluded that public interest would be disserved, because the injunction would take

[280] Riley & Allen 2015 p. 769–770.
[281] *Id.* p. 772.
[282] In the practice of the ITC it has been stated that merely the fact that the infringing activity is wide-spread does not mean that public interest forbids the grant of an exclusion order. This implies that the fact that e.g. many people are used to the infringing version of the product should not play a part in the public interest consideration. Overall the ITC's recent reasoning and practices show that it is more willing than before to take into account public interest. These considerations might have a "spillover" effect to the district courts dealing with domestic infringement cases, and thus increase similar argumentation in those instances. Even though these two forums do not directly communicate, the course of argumentation used by involved parties is very similar. One issue with these new trends has been the problem of how public interest concerns can be argued successfully at the court. See Nicolic 2017 p. 129–130; Riley & Allen 2015 p. 758–765; ITC Investigation No. 337-TA-543 p. 156.
[283] Rachlin 2014.
[284] 872 F.3d 1367 *Amgen* v. *Sanofi* (2017).
[285] Stiefel & Carter 2016 p. 4.
[286] 872 F.3d 1367 *Amgen* v. *Sanofi* (2017).

a helpful drug off the market. The Federal Circuit noted that with this logic pharmaceuticals would never merit an injunction, because it would always reduce the available options for patients. It stated that the "infringer cannot escape an injunction merely by producing infringing drugs" and the public interest of having multiple suppliers of a drug is not appropriate for denying an injunction.

Overall, *eBay* has not had a significant effect on the availability of injunctions on the life science sector. Injunctions are still frequently granted, but the patentee must put more effort in giving reasons why the grant is justified. In the most typical cases of an infringing generic product, it is fairly easy to substantiate irreparable harm and inadequacy of other remedies. It is the public interest factor that might sometimes override the patentee's right to exclude. As seen in the above examples, these cases are relatively limited and more likely to occur in the context of medical devices than pharmaceuticals. Yet, it cannot be ruled out that such arguments would also be successful in a traditional pharmaceutical litigation.[287] Especially the prospect of a pharmaceutical becoming unavailable due to an injunction would seem to disserve the public interest. From these perspectives we move to consider Europe.

4.5 Will the EU Adopt Discretion?

4.5.1 Basis for Exercise of Discretion in Europe

4.5.1.1 Interpretation of the Enforcement Directive

The analysis in section 4.2 showed that the Enforcement Directive does not impose any requirement of equitable discretion nor have European countries otherwise implemented such a provision. Thus, a similar kind of shift as in *eBay* seems at first highly unlikely to occur in Europe. After all, the *eBay* interpretation was based on the discretion explicitly imposed in the Patent Act. However, the strengthening of human rights concerns and the existence of Article 3 should make it possible to adopt a more discretionary approach at least in cases where human rights are involved.

The UK provides an example of how discretion might be exercised within the framework of the Enforcement Directive – with the reservation that there injunctions are subject to equitable discretion like in the USA. In the UK common law system, injunction is an equitable remedy,

[287] Stiefel & Carter 2016 p. 5.

meaning that by default the court should exercise discretion in awarding it.[288] In practice, the case law has substantially limited this discretion and established that injunctions should be granted if a valid right has been infringed.[289]

Despite this main rule, Article 3(2) of the Enforcement Directive has been directly referenced in UK courts and proportionality has been considered.[290] In *HTC* v. *Nokia* it was stated that the exercise of discretion in granting injunctions is subject to the conditions of Article 3(2), including proportionality and dissuasiveness.[291] Recently the Supreme Court touched upon the issue in a case[292] stating essentially that the standard test (called *Shelfer* criteria) for awarding remedies was outdated and the lower courts should be more flexible in deciding between injunctions and monetary damages.[293] For now, it is still the infringer who must show that the injunction would be grossly disproportionate. Although the UK is more discretionary than the European average, there is a significant difference to the US practice, where it is the patentee that must show entitlement to an injunction.[294] If these recent developments continue, the UK might be tempted to look at the USA for guidance on how to implement a discretionary framework.

The CJEU's *Huawei*[295] decision does not apply the Enforcement Directive, although it refers to it. The case could have contained more discussion on the Article 3 requirements (fairness and proportionality), since the case was about which remedies should be available for use in the specific context of FRAND license negotiations.[296] That being said, the case *was* specifically about FRAND negotiation duties, so it does not help much in evaluating discretion of the court or the content of public interest generally.[297] It does not really address granting injunctions. It is still frequently cited in this context because it combines a competition law approach to patent enforcement practices, where the use of injunctions is very relevant. Competition law is also

[288] Marfe et al. 2015 p. 185.
[289] Bennet – Roux-Vaillard – Mammen 2015 p. 23.
[290] Marfe et al. 2015 p. 186, Cornwell 2018 p. 493–494.
[291] EWHC 3778 (Pat) *HTC Corporation* v. *Nokia Corporation* (2013) para. 26–27.
[292] UKSC 46 *Coventry* v. *Lawrence* (2014). The principles governing injunctions have for a long time stemmed from real estate cases.
[293] UKSC 46 *Coventry* v. *Lawrence* (2014) paras. 119 and 161.
[294] Marfe et al. 2015 p. 186.
[295] C-170/13 *Huawei Technologies Co. Ltd*. v. *ZTE Corp.* (2015).
[296] Picht 2016 p. 370.
[297] *Id.* p. 371.

meant to promote public interest, although it employs a completely different toolset than those of patent law or human rights.[298] However, it is generally not deemed suitable for delicate balancing decisions because of its roughness.[299] *Huawei* does not in any way correspond to *eBay* type discretion, which is much wider and more general.[300] The situation could change if the CJEU were faced with another preliminary question that would specifically be about injunctions and balancing them with public interests.

4.5.1.2 Preliminary Question to the CJEU

The CJEU's approach to balancing the property and liability rules has experienced some shifts in the past decades. Based on its early practice, the court could be accused of purpose-oriented interpretations, since it readily referred to the TRIPS Agreement and WIPO treaties to strengthen trade-related rights, but left out references to e.g. the ICESCR.[301] Even when the case at hand was ultimately about a conflict of fundamental rights, the CJEU did not engage in extensive discussion of balancing, but simply stated that limitations are justified for the protection of IP.[302] This approach was essentially about protecting the EU legislator's intentions.[303]

Since then the CJEU has adopted a more active role in promoting approximation of IP laws and their interpretation in harmony with human rights. This development has been most prevalent in copyright, because despite extensive EU regulation of the topic there are still significant disparities in the national frameworks.[304] The CJEU has turned to emphasize the existence of a fair balance between conflicting interests,[305] although the use of human rights argumentation has remained quite selective.[306] The Court could easily put more emphasis on other human rights and thus shift the fair balance towards wider interpretation of exceptions.[307]

---

[298] Barnes 2018 p. 49.
[299] Oker-Blom 2013 p. 1362–1363. Competition law works better as an additional means of intervention for situations that IP law cannot handle.
[300] Picht 20156 p. 371.
[301] Mylly 2015 p. 109.
[302] *Id.* p. 110.
[303] *Id.* p. 112.
[304] *Id.* p. 118.
[305] *Id.* p. 122.
[306] *Id.* p. 126.
[307] *Id.* p. 131. However, it can also be argued that the balancing approach does not address the issue properly and instead we should talk about justifying interferences from the perspective of lawfulness, legitimate aim and proportionality (according to the traditional doctrine for limiting human rights). The conceptual approach here

Because enforcement measures are harmonized in the EU, the CJEU could be confronted with a question about the availability of injunctions.[308] The CJEU probably would raise up relevant human rights concerns, but it must be assumed that its starting point would be wide patent rights including a strong right to exclude. It might take the easy way and simply rely as a main rule on the enforceability of valid IP rights.

Proportionality might arise more concretely if there were an important public interest supporting the denial of injunction. The CJEU could say, relying on the CFR and possibly also the ECHR and ICESCR, that a fair balance must be struck between protection of the patentee's property and the public's right to health and this might sometimes mean that injunction should not be granted. It would seem weird that the arbitrary exercise of exclusion could override central human rights interests, especially since there is the possibility to rely on the liability rule and monetary compensation. The CJEU probably would confirm the relativity of the patentee's right to exclude like it has confirmed that the protection of IP under the CFR is not absolute.

This prediction is supported by the notion that the CJEU would have to take into account the founding treaties. Article 168 TFEU requires that a high level of human health protection is ensured in all EU policies. Since patent enforcement has been harmonized, the availability of injunctions is an EU policy subject to the interpretations of the CJEU. If the CJEU were to state that injunction must be granted in all infringement cases,[309] it would not be ensuring a high level of human health protection in this particular policy. Hence, it must be concluded that the CJEU could (or at least should) not rule out the possibility of health interests preventing the grant of injunctive relief. This would be consistent with the "balanced interpretation" of the Enforcement Directive as described by Norrgård.[310] This means that the interpretation should not be mechanical, but the context of individual cases as well as human rights should be taken into account. In practice this interpretation corresponds to the discretionary approach.

---

would be different from balancing competing interests, but it might not affect the concrete outcomes. See Peukert 2015 p. 141.

[308] Formulated e.g. as whether a national court has the authority not to grant an injunction, if it would lead to a pharmaceutical product becoming unavailable for patients, taking into account Articles 3 and 11 of the Enforcement Directive as well as the relevant human rights provisions concerning health and property.

[309] Apart from FRAND cases, of course, where the CJEU has already recognized the existence of relevant public interests.

[310] Norrgård 2005 p. 511–514.

At this point it can be concluded that the current European system provides adequate tools for the exercise of discretion, even though injunctions (especially for pharmaceutical patents) are still issued as a matter of course in national court practice. The realization of health rights could be used as a discretionary limitation in the grant of permanent injunctions for pharmaceutical patents in the EU by applying human rights law and Article 3 of the Enforcement Directive. However, this is unlikely to become a practice unless a revolutionary case emerges – one that would change the established practice *eBay*-like.[311] The CJEU could potentially make a turn like that if it were presented with appropriate preliminary questions. Still, this must not be taken for granted, because sometimes the CJEU has been quite reluctant to give clear guidance on hard cases.[312] Also cases of some prestigious national Supreme Courts could have an effect on the European level, although they would not bind other Member States. It seems, though, that such a decision would involve interpretation of the Enforcement Directive to an extent that would require referral of a question to the CJEU. The forthcoming Unitary Patent System also provides some interesting options, as will be discussed next.

4.5.2 Unitary Patent System – Limited Discretion?

4.5.2.1 UPC's Discretion in Granting Injunctions

The Unitary Patent System has been making its way into reality for several years now. There have been a couple of setbacks in the ratification phase, but on paper the system is ready. It has been created through enhanced cooperation blessed by EU Regulations. The major document that sets up the Unified Patent Court (UPC) – the UPC Agreement (UPCA) – is an international treaty open for EU Member States. It is thus institutionally independent, but nevertheless reserves a special role for the CJEU in the interpretation of EU law (Article 21 UPCA).

The UPC will also start from the patentee's right to exclude others (Article 25 UPCA). Article 63 UPCA deals with permanent injunctions stating that the UPC "may grant an injunction". The

[311] The other option would be that a change is adopted little by little without major political discussions. These days the developments in European constitutionalization (in this case proper awakening regarding health rights) seem to be caused by "responses to overt crises and inconspicuous incrementalism". The latter is also possible, but seems unlikely or at least hopelessly slow because established case law so profoundly prioritizes the patentee's interests. See Tuori 2018 p. 49.

[312] Norrgård 2010 p. 16–19. Norrgård views somewhat skeptically the willingness and capability of the CJEU to give guidance on hard balancing questions. This view is based on the CJEU's handling of the case C-275/06 *Promusicae* and the way it has not voluntarily sought to further harmonize essential aspects of IP enforcement, such as availability of injunctions, despite the ambiguities of the Enforcement Directive.

formulation of this provision does not give much information given the interpretation practice of similar provisions. However, as a main rule the word "may" is used in legal provisions, when options are involved and the word "shall" is used, when there is no room for discretion of the court.[313] This would imply some sort of discretion for the UPC.

What makes the situation somewhat more complicated is the formulation of the provisions concerning preliminary injunctions and monetary damages (Articles 62 and 68, respectively). In case of preliminary injunctions, Article 62(2) UPCA specifically states that the UPC "shall have the discretion to weigh up the interests of the parties and in particular to take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction". The lack of a similar statement in Article 63 implies that there is significantly less discretion in terms of granting permanent injunctions. On the other hand, Article 68 provides that the UPC "shall -- order the infringer -- to pay the injured party damages". Similar language is used in terms of determining patent validity. This wording suggests that there is no discretion in terms of awarding damages, but they follow automatically from an established infringement.[314]

Thus, the wording "may" in Article 63 suggests that the UPC is provided with some discretion in terms of permanent injunctions – although not as wide as with preliminary injunctions.[315] The preparatory committee of the UPC Rules of Procedure (ROP) specifically rejected the need to add the expressly discretionary sentence of Article 62(2) UPCA to the ROP provision concerning permanent injunctions. This decision was recommended on the basis that Article 63 UPCA already grants the court discretion by using the word "may". General guidelines for using such discretion would follow from Article 3 of the Enforcement Directive.[316] This would seem to be in line with the literal interpretation that implies that the grant of injunctions would be the main rule, although not entirely automatic.

The other course of interpretation would be that the UPCA provision merely restates what the Enforcement Directive and TRIPS Agreement already require, and there would not necessarily be significant discretion. Established principles of Member States and the lack of discussion

[313] Marfe et al. 2015 p. 187.
[314] *Id.* p. 187–188.
[315] Bennet – Roux-Vaillard – Mammen 2015 p. 26.
[316] ROP Digest 2014 p. 93–94.

about these questions in the UPCA drafting phase speak for this interpretation.[317] Partly in support of this view, the Legal Group of the Preparatory Committee has stated that "where the Court finds an infringement of a patent it will under Article 63 of the Agreement give order of injunctive relief. Only under very exceptional circumstances it will use its discretion and not give such an order."[318] This presents injunctions clearly as the main rule. This statement is also not in contradiction with the above interpretation of discretion that should only be exercised in limited circumstances. The Preparatory Committee has stated that "Article 63 of the Agreement provides for a general discretion to grant a final injunction",[319] which further supports the view that the UPC might intentionally be well equipped to balance the right to exclude with other relevant interests.

It is also clear that no *eBay*-like criteria were meant to be put in place and such interpretation would be quite far-fetched.[320] Introduction of *eBay* criteria into the ROP was suggested in public consultation, but this suggestion was rejected by the Preparatory Committee.[321] Thus, it seems that the UPC would not be intended to exercise general discretion in all cases. Rather, it would be authorized to evaluate the proportionality and appropriateness of remedies and possibly deny an injunction in individual circumstances. The right to exclude would remain the main rule, but the UPC would be equipped to keep an eye on how public interests are affected by its judgments.

4.5.2.2 Factors Affecting Exercise of Discretion in the UPC

There are several factors worth mentioning in the context of UPC's discretion in granting injunctions. First there is the question of whether the closer rules regarding discretion should be drawn (exclusively) from Article 3 of the Enforcement Directive. Some would like to conclude that there would be no way for direct application of the Article 3(2) proportionality requirement in the UPC.[322] This would be because proportionality is not the only requirement in the provision: it also requires that remedies be effective and dissuasive and not create barriers to legitimate trade. The requirements of effectiveness and dissuasiveness seem to pull the balance

[317] Marfe et al. 2015 p. 188.
[318] Preparatory Committee 2014 p. 11.
[319] ROP Digest 2014 p. 95.
[320] Marfe et al. 2015 p. 188.
[321] ROP Digest 2014 p. 98.
[322] Marfe et al. 2015 p. 189.

into opposite direction from proportionality.[323] This of course applies equally to interpretations of the CJEU and national courts and is one of the main obstacles in concluding that the right to exclude was meant to be more relative and subject to balancing. It is possible to read Article 3 as mere description of the provided measures instead of a restriction upon them.

Moreover, the existence of discretion does not guarantee that the UPC would be willing to engage in extensive analysis of human rights. A specialized patent court might be both reluctant and incompetent to make such decisions. It might be recommended that the statutory rules should be more unequivocal as to which factors should be taken into account in the balancing. Then again, many stakeholders have expressed that it would be highly undesirable to create a statutory discretion system. Instead the possible power to exercise discretion should be left for the UPC to interpret and establish.[324] This would be consistent with the UPCA, although somewhat in tension with current continental practice.[325] Luckily, the UPC will be an entirely new and independent forum that is not formally bound by national interpretations of the past.

Despite this seemingly clean slate, it has been speculated that the backgrounds of the judges that deal with the first major UPC cases would have a big effect on what the UPC's case law will look like.[326] In discussions with judges about the UPC, it turned out that most judges thought that discretion in granting injunctions existed and proportionality should be considered according to Article 3 Enforcement Directive.[327] Thus, the first wave of cases hitting the Court might leave a permanent mark on its practice depending on what type of cases those are. If the first years of the UPC go without any cases where the application of discretion would be appropriate, the Court might become more unwilling to exercise it even in cases where it would be justified. It seems that much depends on who will decide which cases in the early days of the new tribunal.

A weakness of the UPC from the realization of health rights perspective is its strong reliance on expert judges. Unlike the Federal Circuit in the USA, the UPC judges will not be exposed to other than patent cases. This puts them in danger of becoming biased and only able to take into

[323] Although they can also be given a less dramatic meaning. For a more detailed analysis of these criteria and balancing based on them, see Norrgård 2010.
[324] Marfe et al. 2015 p. 189.
[325] *Id.* p. 190.
[326] Russell & Churi 2016.
[327] Jelf 2017 p. 10.

account concerns stemming from within the patent system. Other EU values like human rights – including public health – might be left in the shadow. Especially the non-lawyer experts might be incompetent in addressing non-IP related legal arguments and concerns. Taking into account this isolation, it can be held particularly questionable that interference by the CJEU has been made so marginal.[328] As a conclusion, it seems that the application of discretion in the UPC is full of uncertainties that will only begin to resolve once the court starts to operate.

4.5.3 Prospects for Pharmaceutical Patents

4.5.3.1 Pharmaceutical Patents in the Unitary Patent System

The UPC system is of interest especially for innovative pharmaceutical companies, because they regularly seek protection in the entire EU.[329] On the other hand, the system might seem tempting for generic companies to try and centrally revoke an important patent.[330] As a limitation, the UPC does not have jurisdiction over nationally granted patents, but only those granted centrally by the EPO.[331] Moreover, patentees have the right to opt out from the jurisdiction of the UPC (Article 83(3) UPCA).

This possibility to opt out was promoted especially by the pharmaceutical industry, which has been skeptical about the UPC.[332] The system seems dangerous, because the upcoming practice of the UPC is not known. Innovative pharmaceutical companies are not willing to risk their most valuable assets being invalidated by a single judgment of the UPC.[333] They are expected to use the opt-out option to protect their most important patents from central attack until they can be sure that they receive beneficial treatment in the UPC.[334]

This is interesting from the point of view of general popularity of the UPC, because pharmaceutical companies represent one of the few industries that would clearly find savings in having one unitary patent instead of a bunch of national patents.[335] Additionally, they already engage in multi-jurisdictional patent litigation, so they were initially seen as a promising target

[328] Dreyfuss 2015 p. 157.
[329] Johnson 2015 p. 189.
[330] *Id.* p. 180.
[331] Fox 2018 p. 85.
[332] *Id.* p. 86.
[333] Johnson 2015 p. 189.
[334] Fox 2018 p. 86.
[335] *Id.* p. 87.

group of the new system.[336] Reactions of the originator companies are an important factor in determining the actual volume of UPC patent litigation.[337]

Opting out of the UPC's jurisdiction would be a purely defensive act. Moreover, it is not final: a patent can be re-entered into the Unitary Patent System as long as no national proceedings have been started.[338] This is also important, because the innovator companies are frequent litigators. A bit over half of European pharmaceutical litigation starts as an infringement action from the patentee.[339] This tells us that the companies also seek effective enforcement in addition to shelter from centralized revocation.[340] A pan-European injunction would be a valuable tool in keeping out infringing products, so pharmaceutical companies are likely to carefully keep an eye on the UPC independent of possible initial opt-out.

If the UPC turns out to exercise wide discretion in granting injunctions and the national practices do not change, innovator companies would most likely prefer to litigate in national courts that would not put too much emphasis on public health concerns. Of course, this situation might change by a preliminary ruling of the CJEU – which could theoretically originate either from a national court or from the UPC. Correspondingly, very automatic injunctions would encourage to move patent litigation from national courts to the UPC for the sake of efficiency.

Here lies also a dilemma: will the UPC be tempted to lure in more cases by adjusting its argumentation to be favorable for e.g. innovative pharma so that they would bring in more cases?[341] Or will national courts do so? Especially in its early days, the UPC will merely be one more alternative tribunal in Europe and parties will weigh carefully the potential risks and benefits of litigating there.[342] Depending on how secured the position of the UPC becomes and how many cases flow in there naturally, there might be no need for flattery. However, as an alternative court, there is a high risk that it will experience some form of pressure to make itself an attractive venue in the eyes of "clients". Then again, the UPC is equipped to be better than

[336] *Id.* p. 89.
[337] *Id.* p. 90.
[338] *Id.* p. 91.
[339] Pharmaceutical Sector Inquiry 2009 para. 586.
[340] Fox 2018 p. 91.
[341] See Dreyfuss 2015 p. 156.
[342] Fox 2018 p. 89.

national courts in other aspects such as speed and specialization, so it might attract patentees also without purpose-oriented interpretations.[343]

4.5.3.2 Application of eBay *Reasoning to European Pharmaceuticals*

Alongside with the above prospects relating to the UPC, it needs to be considered how the discretionary approach could be applied to pharmaceuticals in European courts – be it a national court, the UPC or the CJEU. In this section, the arguments of US *eBay* case law will be tested for suitability in the discretion framework of the EU. As will be seen, most of the US arguments fit quite well into the legal framework of the EU, although some things have traditionally received differential emphasis.

As discussed above, irreparable harm (and inadequacy of other remedies) often speak for the grant of an injunction in pharmaceutical patent cases. The irreparable harm factor has been addressed in Europe mostly in the context of preliminary injunctions. Pharmaceutical patents have been quite strong in these cases.[344] Just like in the application of the *eBay* criteria, it is relatively simple for pharmaceutical companies to show irreparable harm in case a generic product is launched. The existence of such harm seems to tip the scale of proportionality, effectiveness and dissuasiveness towards injunctions. Hence, it is reasonable to stay the assumption that issuing an injunction would remain the main rule in Europe even in case discretion exists. Injunction would usually be proportional for the protection of a valid IPR. Only in special circumstances would other interests receive serious consideration.

As for the public interest, we can start from the presumption that "serving" public interest would not be explicitly required in the EU, either, although sometimes injunctions undoubtedly do so.[345] However, disserving it might make an injunction disproportionate. Under *eBay*, making a medically important product unavailable to patients has been deemed to disserve the public interest and to justify not issuing an injunction.[346] This might also work as a basis for denial in Europe. In pharmaceutical patent contexts this might occur if the infringing generic product is

[343] *Id.* p. 94. Quality of judgments is an important factor in deciding where to litigate – not just the win rate. Crompton 2010 p. 47.
[344] Whiting & Lorenzo 2016 p. 26.
[345] I refer to the indirect public benefits resulting from strong incentives to innovate and to publish inventions, to name some.
[346] See section 4.4.2.2 above.

slightly different from the original in ways that make it more suitable to some patients.[347] If the (potential) unavailability of a specific pharmaceutical were a result of more or less arbitrary exercise of the right to exclude, a conflict between health rights and property rights might be recognized and addressed according to the described principles. Of course, application of this reasoning usually requires that the infringing product already is on the market and is used by patients. Otherwise it would be much harder to show that patients would have a health rights based interest in keeping the infringing product available.

Especially before the *eBay* ruling, the priority of limited term exclusive rights was recognized as a conscious choice of the lawmaker in the USA. At that time, many public interest arguments against injunctions could be overturned by competing public interests related to the patentee: denial of an injunction would distort the patentee's economy, which might lead to loss of jobs and investments. The argument was that this would disserve the public interest more than the short period when there was no free competition on the specific product.[348]

This is a relevant argument that might have some room also in European cases. The functioning of the market – undoubtedly the EU's favorite argument[349] – might be deemed to require clear and enforceable rights. In the traditional sense, dysfunction of the market would obviously disserve the public interest and such dysfunction might be caused if viable businesses are exposed to unnecessary insecurity – even if such insecurity would promote competition. This argument can be overcome by emphasizing the meaning of timely access to medicine and the initial idea to balance IPRs with other relative interests instead of treating the statutory rights as absolute.

This chapter can be concluded by stating that judicial interpretation definitely makes it possible to introduce discretion into grant of injunctions in the EU. There are many ways and forums how and where such discretion could be framed. No single way can immediately be identified

[347] There is evidence that generics do not always entirely correspond to the patented medicines, although by definition they are "essentially similar". Their formulation and efficacy may vary compared to the patented product and also between different generic products. Sometimes different patients prefer either a generic or the patented drug depending on e.g. the details of their condition. See Beran 2016.
[348] Merges & Duffy 2011 p. 949–950.
[349] Ojanen 2009 p. 1113. In traditional EU law, internal market freedoms and the subsequent functioning of the market enjoy primacy over other goals. Recently, more room has been allowed for interests of non-economic nature, but market-related arguments still dominate the question whether something is within the EU's competence or not.

as the best one. A preliminary ruling of the CJEU seems the smoothest and most effective way, but there are no guarantees that such case would ever be presented to the CJEU, so other options must be left open. For pharmaceutical business a discretionary system would cause more uncertainty, but it would not necessarily mean weakening the right to exclude in standard cases. There are many factors affecting the final balance of each case. Those factors will be analyzed more thoroughly in the next chapter, which will discuss the balance between issuing injunctions and emphasizing health rights.

5. Introducing Health Right Considerations into Patent Law

5.1 How to Balance

In this chapter I will consider how the discretion could be applied in practice and where the balance should be struck. Special focus will be on the question when it would be appropriate to deny injunctive relief. Different aspects will be considered. The viewpoint of this chapter will bring in more human rights rhetoric after the patent law focused approach of chapter 4. In chapter 4 it was concluded that the basis for discretion exists in the EU, too, but it has not been brought to legal practice. It has also been established that the exercise of discretion requires proper balancing of the interests of the patentee and those of the public. The aim of this chapter is to find some practical guidelines for establishing that balance.

One interesting aspect of the quest is whether a patentee should have done something "wrong" to be "deprived" of the right to exclude. Or should grounds for denial of injunction be independent of the patentee's conduct? One such wrongdoing could be that a pharmaceutical company would be in breach of an obligation to comply with human rights. Another reason could be that public health considerations require it independent of what the patentee does. The meaning of the conduct of the patentee is the underlying theme of this chapter.

Another theme that is raised in this final chapter is the value-based choices that must be made in striking the balance. So far the values have not been directly addressed, although they have been present in the weighing discussion. Here they will be discussed along with the different approaches identified to make conclusions about possible courses of action.

As concluded in the above analysis, European laws give courts discretion in granting injunctions – or at least they do not rule it out. It remains somewhat cloudy how this theoretical discretion

could be put to use and whether it should be done in any typical cases. Courts have the authority to take into account human rights considerations, since they are part of the applicable law. When the applicable patent law does not include an absolute obligation to grant an injunction,[350] it seems that EU courts could well discuss the public interest implications of an injunction request. One scenario that might trigger the start of a new practice is an extreme case, where human rights interests would be so manifestly compromised that the court simply could not prioritize the patentee's rights. Such a case could also affect the argumentation of cases where the imbalance of interests is less extreme.

5.2 Corporate Human Rights Compliance

5.2.1 Do Pharmaceutical Companies Have Human Rights Responsibilities?

The question discussed in this section is whether there are or could be any human rights responsibilities for pharmaceutical companies and how these might be enforced. The idea is that if a company could be held to be in breach of its human rights obligations, it would not be granted an injunction. The threat of not being able to enforce a patent would then force companies to pay more attention to the human rights implications of their products, in practice to value appropriately the interests of patients in having access to the patented pharmaceuticals. Availability of injunctions could thus be used to encourage desired conduct – *if* corporations have human rights obligations.

Currently only states must comply with international human rights obligations. Multinational corporations are not legally bound by human rights obligations, although one can argue that they are morally obligated to respect human rights. Such moral obligation can only be supervised and enforced by soft law mechanisms, like different guidelines.[351] There are no direct mechanisms how human rights could be enforced on private companies.[352] Yet, the borderline between states and private entities has clouded in recent decades as states have transferred their duties to private companies and big corporations have gained a lot of power.[353] It can be argued that an individual is as vulnerable before a huge corporation as it is before a state entity, and for

[350] Such an absolute obligation would imply that an appropriate balance has already been struck by the lawmaker. Usually this is not the case, as discussed above.
[351] den Exter 2010 p. 135–136.
[352] Ahmadiani & Nikfar 2016 p. 6.
[353] Hestermeyer 2007 p. 95.

this reason some of the human rights obligations of states should extend to such corporations.[354] In principle the WTO is also not bound by human rights, except those of *jus cogens*. This has been criticized a lot.[355]

According to the interpretation of the CESCR, all members of society, including private businesses like pharmaceutical companies, "have responsibilities regarding the realization of the right to health".[356] Unfortunately it has not specified what these responsibilities are exactly.[357] Many officials have recognized that the "pharmaceutical sector has an indispensable role to play in relation to the right to health and access to medicines" and specific pharmaceutical companies have very constructively contributed by their access programs and by participating in initiatives.[358] Many scholars also stress that there is a strong need for enhanced corporate responsibility in the pharmaceutical world in terms of access to medicines.[359]

Strict interpretation of these statements would require that the pharmaceutical industry pay more attention to social responsibility instead of just enhancing shareholder value.[360] However, it is recognized that such requirements are disproportionate without any specific guidelines on desired practices.[361] The UN pharmaceutical guidelines[362] would prohibit inter alia lobbying for extended patent protection and refusal to license pharmaceutical patents. Compliance with these requirements would mean very fundamental changes in business strategy to many innovative pharmaceutical companies.[363] This is not possible without detailed guidance on what is

[354] *Ibid.*; Walkila 2015a p. 184–184. It has been argued that human rights should have horizontal effects, because they cannot be realized fully if private parties may violate each other's rights.
[355] Hestermeyer 2007 p. 101–102. This is why the WTO dispute settlement system would likely find general international law more persuasive than arguments concerning e.g. the ICESCR. General international law contains a principle of access to essential medicines and this could be employed by the WTO machinery in a similar manner as the CJEU started to employ human rights law before it was officially adopted as a part of the EU legal order. See Hestermeyer 2007 p. 222, 288–289.
[356] CESCR 2000 para. 42.
[357] Lee & Hunt 2012 p. 221.
[358] UN Report 2008 para. 23.
[359] den Exter 2010 p. 138.
[360] *Id.* p. 133.
[361] UN Report 2008 para. 27.
[362] *Id.*, Annex para. 26–32.
[363] den Exter 2010 p. 133.

expected.[364] Abstract responsibilities tend to not lead to very efficient outcomes, especially since the company management is also responsible to comply with the business judgment rule.[365]

According to some views, corporate human rights responsibilities would basically obligate pharmaceutical companies to make all novel medicines as accessible as possible in terms of price, availability and timing.[366] Under this obligation, a company should even amend its patenting practices if they contravene health rights.[367] This is a problematic statement, since it does not address the role of financial sustainability in pharmaceutical business. Especially while health rights promotion measures are mere voluntary suggestions, company management cannot put into practice extensive schemes that are contrary to established practice and business interests. Even when admitting that companies are allowed to make "a reasonable profit",[368] many questions remain. Who decides how much profit is too much? Are all R&D costs taken into account? Does this actually differ in any way from a general abuse of rights prohibition? If the only material effect of these rules would be that the pricing of pharmaceuticals is not allowed to be extravagant, one could argue that there already are mechanisms that make sure it is not.[369]

In the UN Guiding Principles on Business and Human Rights it is stated that "business enterprises should respect human rights".[370] This "respect" can be held as the baseline of what is required.[371] The Principles further explain that to fulfil the responsibility to respect companies should have in place a human rights policy, exercise human rights due diligence and be ready to remedy any adverse human rights impacts they cause.[372] According to the Institute for Human Rights and Business, companies operating in areas that closely affect the realization of certain

---

[364] Lee & Hunt 2012 p. 221.
[365] This refers to the "rule" that business decisions of company management are deemed appropriate in relation to shareholders if they could be justified from a business perspective at the time they were made. If this is the case, the management could not be held liable for losses that occurred due to the decision. The business judgment rule is an American way of presenting the principle; Europeans tend to speak of the management's duty of care. See e.g. Airaksinen – Pulkkinen – Ratinaho 2018b p. 808, Schulten 2004 p. 624–634.
[366] Lee & Hunt 2012 p. 228.
[367] *Ibid*.
[368] *Ibid*.
[369] E.g. the national pricing boards make sure that prices are reasonable. Overall, the patent system is ill suited for price containment and any attempts to utilize it for such a purpose seem quite utopian. Yet, the affordability issues related to novel therapies increase the pressure for transparency and strict scrutiny when it comes to pharmaceutical pricing. These issues and the above mentioned questions have been discussed in EXPH Opinion 2018 that addresses contemporary issues in medical innovation.
[370] UN Guiding Principles 2011 para. 11.
[371] Lee & Hunt 2012 p. 223.
[372] UN Guiding Principles 2011 para. 15.

rights – such as the right to health in the case of pharmaceutical companies – should have more responsibilities than the basic respect obligation.[373] Overall, it seems that no concrete obligations exist, but the consensus seems to be that some form of human rights consideration can be required of the pharmaceutical industry. There is no unanimity on the extent of this consideration.

5.2.2 How to Enforce Human Rights Compliance

If there are some human rights obligations for pharmaceutical companies, they cannot be directly enforced at the moment. However, they can be incentivized. There are constructs that would tie human rights compliance with some concrete outcomes to the company i.e., noncompliance would be indirectly punished. This could be framed in multiple ways, the most important of which will be discussed here briefly.

Den Exter has proposed that granting patents should be subject to conditions of social responsibility.[374] For pharmaceuticals this would mean ensuring access to medicines by appropriate pricing and voluntary licensing. Such a requirement would surely interfere with current industry practices, but could be justified from a human rights perspective.[375] This approach resembles the general social contract or social license framework that can be used to describe the idea of patent rights.[376] However, the realization of such requirement would require legislative changes and it could only be applied to future patents.[377]

One issue that could be relatively easily incentivized is the development of medicines to neglected diseases. Based on mere business judgments the R&D activities of companies tend to focus on curing diseases typical for large amounts of western world patients that are able to pay for expensive treatments or insurances.[378] These include long-term treatments for chronic diseases and cancer, whereas cures for acute or very rare diseases are not as tempting commercially.[379] This issue of neglected diseases has resulted in calls for corporate human rights

[373] IHRB 2009 p. 5.
[374] den Exter 2010 p. 136–137. These conditions might mean that a patent could be revoked or not enforced if it were "misused".
[375] *Ibid.*
[376] Lee & Hunt 2012 p. 227–228.
[377] It might not require amendments to TRIPS, if it could be framed to fall within the public health exception. This makes it a much more appealing solution, although still very theoretical.
[378] Helfer 2015 p. 14.
[379] Ahmadiani & Nikfar 2016 p. 3.

compliance requirements and regulatory incentives.[380] Companies could be required to take part in R&D concerning neglected diseases, either directly or by funding such activities.[381] However, this is not exactly an issue of patent law, and it concerns primarily developing countries, although some rare diseases remain neglected also in the EU.

Assuming there are corporate human rights responsibilities, it would seem convenient to control the availability of injunctions as an insurance of compliance. The WTO rules and TRIPS Agreement prevent any major interference with patent rights and their exercise, so wealthy states only have limited tools in enforcing or promoting health rights.[382] Restricting the use of injunctions would not directly interfere with current IP treaties. It would seem odd if pharmaceutical companies were held accountable for very high standards of human rights compliance, but at the same time they could exclude infringers by obtaining injunctions without the human rights aspects being concerned in the infringement trial. In most cases this interpretation would not even change the legal state. As seen in the above analysis, it is hard to come up with patent law proof arguments why injunctions would not be justified in standard pharmaceutical cases. This is because the right to health does not prevail over property rights in a normal, non-urgent or non-vital situation. The interests of the patentee become the primary concern in such a setting.

At the moment the easiest tool for limiting effects of counter-productive practices would seem to be competition law.[383] It does not directly compromise the status of patent rights, but it could be employed more vigorously to prevent strategies that postpone market entry of generics post-expiry. It might even be suitable for the realization of the principles suggested by den Exter, described above. This would basically be a policy change in how we want companies to act and what conduct we deem acceptable under the current values. Also NGO-originating "naming and shaming" and other penalizing practices are mentioned as tools to make human rights promotion profitable for pharmaceutical companies.[384]

---

[380] *Ibid.*
[381] Lee & Hunt 2012 p. 225. Arguably, this would awake huge controversies.
[382] Ahmadiani & Nikfar 2016 p. 4. For developing countries, more freedom is allowed, because the public health situation is typically much worse and thus also bigger interference with IPRs is justified.
[383] *Ibid*. National authorities have limited competence to interfere with legal pursuit of patent protection, so it is natural to aim limitations at how patents are used in practice. See also Minn 2018b p. 109.
[384] Ahmadiani & Nikfar 2016 p. 5. These practices strike at the public image of the company and try to build public pressure so that companies would change their behavior. One weakness in this setting is that consumers do not

Most radical voices have suggested that pharmaceutical companies should be required to sign human rights treaties so that they could officially be monitored and held accountable.[385] This would mean a fundamental change in the human rights framework, if any legal person could be obligated with human rights. This appears as a rather bad idea that would distort some basic principles. After all, companies are dedicated to making money for their owners. Companies cannot be turned into charities by requiring that they actively promote human rights. They must base their decisions primarily on business perspectives and corporate benefit to stay viable. It should be for the states to set out the framework within which the pursuit of profit can happen and what conduct is allowed.[386]

Overall, any serious introduction of corporate human rights compliance into the legal system would require substantial efforts from many different parties.[387] Thus, it does not seem the primary option for some relatively minor interest balancing. Admittedly, the concerns of developing countries can be more serious, but in this case focus is on developed countries, where the basic level of health rights is generally quite well materialized. The availability of injunctions might provide appropriate balancing for the kind of extreme situations where interference is deemed necessary.

From this analysis it can be concluded that there are many ways to incentivize companies to have more interest in public health concerns. It also seems that judicial interpretation – i.e., controlling the availability of injunctions – is not unsuitable for addressing the realization of health rights in the pharmaceutical patent context. If a company takes carefully into account patient interests and has ensured that health rights are realized as far as reasonable,[388] it might

directly choose which pharmaceuticals to use, so they cannot stop buying a product in the same way as with e.g. food products. These strategies have nevertheless worked also on pharmaceutical companies.

[385] *Id.* p. 6.

[386] This is consistent with the general assumption that companies are free to pursue profit as long as they comply with the law. The primary concern of a company is thus "corporate benefit". If there are any special responsibilities, these are set in separate legislation. For example, employees and the environment are protected with separate regulations that set concrete requirements. It is reasonable to assume that possible accountability for the realization of health rights would also be set in more specific legislation, not just human rights treaties or constitutions. However, it is possible for a company to participate in incentives that improve its public image without violating any corporate benefit obligations. These include participation in charities and sponsorships and investments to clean technology, for example, as long as they are not so excessive that they would ultimately be detrimental to the company. This might be the case for a sudden, unnecessary change in business strategy of a pharmaceutical company, because it would almost certainly directly reduce profits and shareholder value. See Airaksinen – Pulkkinen – Rasinaho 2018a p. 28–29, 34–35.

[387] Ahmadiani & Nikfar 2016 p. 6.

[388] Reasonable meaning that there is a fair balance with business realities.

be hard for a court to deny injunctive relief based on health rights arguments. On the other hand, if the business strategy of the patentee neglects patient interests, it might be justified to not issue an injunction in order to allow better access for patients.

This logic would be easy to apply, but it would require the recognition of some obligations of the companies. After all, the denial of injunction would be based on an alleged shortcoming of the company to consider health rights. As discussed, the existence of any such obligations is controversial. Besides, even if a company has done everything right, there might still be cases where an injunction would not be appropriate. These would be cases of compelling public health interests. Those will be considered next.

5.3 Public Health as a Limitation to Patent Enforcement

The goal of this section is to come up with public health related criteria that would justify denial of an injunction without any major malpractices from the patentee's side. Public interest arguments would be a clear way of introducing such rhetoric into patent enforcement. This is a central part of the more general discretion doctrines introduced above, such as the US *eBay* criteria or enforcement of SEPs. The fourth *eBay* factor specifically addresses public interest. This makes consideration of public interest aspects mandatory for all US courts dealing with patent disputes.[389] Despite this step toward public interest considerations, it has remained somewhat unclear what the role of this factor is in practice.[390] According to Riley and Allen, it remains somewhat underused and could be utilized more exploratively.[391] This is all the more true for Europe, where no balancing doctrine is in place.

The CJEU[392] might be in a position to develop a public interest test that would apply under the framework of the Enforcement Directive. Considering health rights specifically, its content might be something like "an injunction should not be granted if it would compromise the health interests of a relevant patient population". In discussions with judges about the UPC, public

[389] Consideration of public interest has moved from the background to the forefront of patent enforcement in the USA. This shift has also been criticized and many have called for refocusing the patent system to the patentee's right to exclude. Despite this it is expected that public interest will be addressed even more in the future. See Allen 2013 p. 1050, 1052.
[390] Riley & Allen 2015 p. 757.
[391] *Id.* p. 753.
[392] Or, alternatively, the UPC, but as discussed above, the specialized patent court is more likely to start off as being favorable to patentees instead of making injunctive relief more discretionary. Also, national courts would not have to follow the UPC's practice.

health was seen as a relevant factor in the balancing required in awarding remedies for health products. The views diverged on whether an injunction should be issued in the specific example given. Some judges would have considered a compulsory license, whereas some would have issued an injunction.[393] This shows that there is indeed balancing and decision-making involved, so even an outspoken balancing rule could have differential applications.

Among the issues debated by the judges were the significance of the affected patient population and the role of financial considerations. Some considered ten affected individuals per million to be a relevant population in terms of public health while others did not. It was also discussed whether the patentee's product being too expensive was a good enough reason not to grant an injunction.[394] Many judges seemed to think that refusal to issue an injunction should never be based on financial factors unless abuse of a dominant position was at hand.[395] This is consistent with the notion that mere patient interest in cheaper medicines is not important enough to override the right to exclude.[396]

While this might be a good starting point, the situation becomes more complicated if it is shown that people become permanently disabled because they could not access a pharmaceutical or a diagnostic test because of its price. At this point it might be reasonable to draw out the arguments concerning the primacy of health rights over property. The closer the pharmaceutical at hand is to an essential medicine or life-saving technology the more justified it would be to lean on the non-derogable human right rhetoric without violating P1(1) and the right to exclude. The situation is trickier if the incomplete accessibility of pharmaceuticals is essentially a result of inadequate allocation of resources to national healthcare systems.[397] Such a setting can hardly be blamed on the patentee, although they will be damaged by it if the primacy of health argumentation in deemed appropriate in the circumstances. The dilemma of matching the

[393] Jelf 2017 p. 13.
[394] *Ibid*.
[395] *Id.* p. 10.
[396] In contradiction with this notion, in a recent Indian case denial of an injunction was based on national economic interests. The Delhi High Court allowed infringement of a patent for manufacturing the product for export and based this decision on the "public interest" in the domestic generic producer's economy. This is a clear deviation from the restriction of public interest arguments to vital drugs and medical interests (the pharmaceutical in question was for treating erectile dysfunction). In effect the ruling resembles granting a compulsory license. See case *Bayer* v. *Ajanta* (2017) and its commentary by Bharadwaj 2018.
[397] Boscheck 2015 p. 226. Countries tend to recognize the need for better healthcare, but cost containment is often prioritized over improving access and quality. This is not only a problem of the developing world.

patients' and the patentees' rights and the realities of national healthcare systems is likely to intensify as more expensive novel therapies make it to the market.[398]

The above example highlights the meaning of factual circumstances. It is often hard to demonstrate that e.g. a national health system would not be able to afford a specific medicine.[399] The patentee tends to enjoy a type of benefit of doubt in the sense that its product is assumed to be accessible enough if there is nothing to compare it with. This is manifested in the US district court practice, where the public interest factor is unlikely to hinder an injunction if the infringing product has not yet made it to the market.[400] In those cases it has not yet had the chance to become the trusted product for consumers – a fact that has sometimes been assimilated with public health interests.[401] In such a case the injunction would not remove a product from consumers' grasp and interfere with acquired benefits, so it is easier to accept. From a patentee's perspective it would be crucial to act fast in the administrative launch phases of the infringing pharmaceutical so that the possible benefits of the infringing product will never materialize for patients. In such a way, also the public interest stays hypothetical and thus cannot be disserved with an injunction.

There seems to be no reason why similar logic could not be applied in a European setting. It would indeed seem contrary to property rights for a court to choose to allow an infringement to happen in the future (when the product is not yet marketed) without any knowledge of whether it will facilitate better access for anyone. An acquired benefit setting is different, because it would require the court to actively remove a health benefit from a patient population. The significance of this population is an important factor in determining whether an injunction would be disproportionate in terms of public health. There will always be someone who is affected, but the threshold should be evaluated on the population level to set a proper balance.

---

[398] Mansnerus 2016 p. 168. Many novel therapies that fall into the category of "advanced therapy medical products" are quite expensive. So far they have been available to only a few orphan diseases, so their budget impact has remained limited. However, as therapies targeting e.g. cancer emerge, national health systems have to make some tough choices. From this kind of setting it might seem really tempting to try and pull down the prices of products by limiting exclusivity. Yet, Mansnerus notes that there is no evidence that exclusivity alone would cause high prices whereas interference with IP rights would constitute a negative incentive for subsequent R&D.
[399] Jelf 2017 p. 10.
[400] Stiefel & Carter 2016 p. 5.
[401] See e.g. case *Johnson & Johnson Vision Care* (2010).

The German Federal Supreme Court has discussed the significance of public interest in its case *Raltegravir* (2017), which concerned grant of a compulsory license for the HIV pharmaceutical raltegravir. German courts currently do not have discretion in granting injunctions, so the defendants of infringement trials have sometimes sought a compulsory license in the name of public interest.[402] In *Raltegravir*, the Court stated that also a relatively small patient population can constitute an important enough public interest, if the unavailability of the drug would cause a big danger to the patients. There were alternative treatments, but the Court held that switching a well-functioning treatment to another poses risks to patients and thus there is a public interest in keeping the existing therapy available. The fact that the infringing pharmaceutical had been on the market for a long time also played a role.[403] The case highlights a flexible and context-dependent interpretation of public health interests and demonstrates that no national emergency is required for health interests to prevail in individual cases. However, earlier case law[404] of the same court has established that activation of the public interest requires special circumstances and this still remains the main rule also according to the *Raltegravir* judgment.

The decision whether an injunction is appropriate in terms of public health is ultimately a case-by-case evaluation. The things that affect it include the size of the affected patient population, the patients' geographical distribution,[405] the seriousness and irreversibility of their medical condition, the urgency of the public health concern, whether there is an alternative treatment and how good it is, whether the case is more about availability or affordability, and what options the national health system has to relieve the situation.[406] These factors must be taken into account in addition to the interests of the patentee. Different conclusions can be made from the same set of facts depending on how e.g. the amount of affected patients is weighed. Thus, the

---

[402] von Falck 2016 p. 352.

[403] Bundesgerichtshof: *Raltegravir* (2017), especially paras. 48–49, 66–71. The case marked the first ever grant of a compulsory license in Germany, although the grant became void as the patent was later revoked. For discussion of the case, see e.g. Slowinski 2018, Otto & Wolters 2017.

[404] Bundesgerichtshof: *Polyferon* (1995) para. 44. The case also concerned grant of a compulsory license, but in this case the grant was not deemed appropriate. The Court mentioned technical, economic, social and medical considerations as factors that can constitute special circumstances (para. 49).

[405] I.e., whether all affected individuals reside in a limited geographical area in a way that makes a big impact on the local level.

[406] The role of the national health system in the equation is not simple. Its choices as to which treatments to pay for and to what extent have implications for patient behavior. For example, providing a treatment for free will increase demand and thus possibly diminish the system's prospects for maintaining current pricing in the future. This is why the national health system might not always be in a position to do anything about a specific accessibility issue. See Morgan 1996 p. 26.

evaluation is very subjective and affected by values. Purpose-oriented interpretations are also possible.[407]

5.4 Securing Stable Business Environment

5.4.1 Effects on Incentive to Innovate

In section 5.3 the different factors supporting intervention in the name of public health were identified. This section concerns the circumstances of the patentee that could affect the justifiability of an injunction. The implications of injunction policy for the stability of business environment and legal certainty are also discussed.

Patents are immensely valuable for pharmaceutical companies and have been described as their "crown jewels".[408] This expression has been criticized to reflect a misunderstanding on the role of patents. According the UN Special Rapporteur, patents are not merely entitlements of the company, but they also come with social responsibilities to e.g. exercise the invention. Exclusivity is a reward for the valuable function the company has performed for society, but the company should also consider the benefits of those in need in its use of the reward.[409] This is a noble idea, but in practice companies tend to treat patents purely as business assets. As such there is nothing wrong with this, but it also creates need for additional controls on patent use.

Above the scope of the right to exclude has been discussed extensively. In general, the scope of patent protection is a key factor in determining the value of patents and R&D efforts. If the scope of patent protection were made significantly smaller, the effects might cumulate with other current problems and produce harmful outcomes in the society at large. One current and worrying phenomenon is that the number of new medicines entering the market has been steadily declining.[410] This number is an established measure of innovation, although its relevance can also be questioned. According to innovative pharmaceutical companies, reasons for the decline include more complex R&D processes, pharmaceutical price regulation and lack of reward for incremental innovation.[411] Weakening the position of innovators in terms of

[407] This notion is based on the fact that the overall effects of health rights in European litigations remain very abstract and negligible. Hervey & McHale 2015 p. 183.
[408] UN Report 2009 para. 107.
[409] *Ibid*.
[410] Pharmaceutical Sector Inquiry 2009 para. 80.
[411] *Id.* para. 1513.

existing, profitable products could significantly undermine the prerequisites for future innovation.[412]

At the same time there are numerous voices that would like to speed up generic products' market entry.[413] According to these views, innovative pharmaceutical companies already have various means to ensure exclusivity, including the regulatory market exclusivities (data and market exclusivity and exclusivities under the orphan drugs and pediatric regulations).[414] In this toolbox, the exclusivity resulting from a patent might not even be the most important.[415] Rather the companies' various "life cycle management" or "evergreening" strategies can compromise public interests by delaying market entry of generic products even after the original exclusivity periods are over.[416]

On the other hand, market entry of generics has already been made easier in many countries. One means for this has been the possibility to use the originator's data as a reference in the approval of a generic version and the implementation of the Bolar exemption.[417] As a result of these policies, virtually all patented medicines receive a generic competitor when the exclusivity expires.[418] This used to not be the case, so at least some of these policies must have been efficient in facilitating competition and better patient access. It should also be remembered that generic companies are also in pursuit of profit. Charity is not their core purpose, so sometimes their conduct can evoke equal criticism as that of innovative companies.[419]

A frequent concern on behalf of the patentees is how they would be incentivized to innovate if there would be no guarantee of exclusivity for the patent term. Excessive use of public interest arguments is seen as a waste of time and resources and the more courts lean on those arguments the likelier it is that the cost-benefit balance of the patent system will be distorted.[420] These

---

[412] However, it has also been argued that the companies' own defensive strategies could be at least partly accountable for the dubious future perspectives. Tuominen 2012 p. 547.
[413] Barnes 2018 p. 62.
[414] Broes et al. 2016 p. 21; Papadopoulou 2018 p. 302.
[415] Papadupoulou 2018 p. 310.
[416] Owoeye & Owoeye 2018 p. 50. For the various strategies required of publicly traded pharmaceutical companies to increase shareholder value see Boscheck 2015 p. 223–224.
[417] Trogan 2005 p. 360. Bolar exemption refers to the use of patented products being allowed for the purpose of carrying out tests necessary for obtaining a marketing authorization.
[418] *Id.* p. 362.
[419] Tuominen 2012 p. 550.
[420] Allen 2013 p. 1087.

views emphasize the careful balance of the pharmaceutical incentive system as a whole and the net social benefits gained from active pharmaceutical development.[421] This is an important notion that is sometimes left in the shadow in typical debates: powerful incentives also support patient interests and health rights indirectly through contributing to better treatments in the future. Exclusivity remains an important incentive that cannot be replaced in an instant.

There are also opposite views. According to Ayres and Klemperer,[422] it would be just as incentivizing in economic terms as the current situation if there would be no absolute exclusivity, but the duration of the "right to get paid" would be longer. This might even be beneficial for society, because the patentee would and could not charge monopoly prices for the limited patent term.[423] This might help solve some access issues for pharmaceuticals, because more people could potentially afford novel medicines sooner. The role of injunctions in creating the incentive to innovate is sometimes taken for granted. It can also be argued that the money received in the form of license royalties or compensation for infringement is a great enough incentive for future inventions.[424] This is an especially convincing argument in the case of non-practicing entities, but it cannot be downright rejected for pharmaceutical patents either.

It seems that although current business strategies lean heavily on exclusivity, it might not be as fundamental a feature as the companies would like to convince to the public. Introducing more characteristics of the liability rule to pharmaceutical patent enforcement would not necessarily mean that an entire industry becomes unprofitable. The strategies of pharmaceutical companies and the counter-initiatives to eradicate undesired practices highlight that the pharmaceutical industry is used to developing new tactics and to balance between fair and questionable competition. Obviously, it would be detrimental if injunctions suddenly became very hard to get without any additional guarantees to the pharmaceutical companies. However, the guidelines suggested in this analysis would largely maintain the current right to exclude and reserve interference for special circumstances. In all cases, appropriate compensation would be

[421] Kuhlik 2004 p. 109. As the date of this reference indicates, the debate over the balance of the incentive system and the social benefits has been going on for some time. Nevertheless, new arguments keep arising as societies change.
[422] Ayres & Klemperer 1999 p. 992.
[423] *Id.* p. 993.
[424] Helm 2006 p. 337–338. Some studies have also shown that the incentive would exist even without any IP protection. The dynamics of publication would merely differ. See Elmahjub 2016 p. 36.

guaranteed. Of course, different interpretations of the same guidelines can occur, so there could be rather a lot of legal uncertainty despite the initial intentions.[425]

5.4.2 Avoiding Denial of Injunction

The discretionary approach to injunctions undoubtedly increases legal uncertainty. There might still be measures that the patentee could take to increase the chances that their interest to exclude is considered a priority. Even if no direct obligations to promote human rights exist, a patentee could take into account health rights with the result that there are no compelling public health interests standing in the way of granting an injunction.

Some pharmaceutical companies have introduced their own health rights programs, which might be interpreted in their favor. Despite adopting such programs, the companies tend to oppose arguments that imply that they would be legally obligated to do so. They admit that health rights are an important concern, but find it hard to imagine how their enforcement could operate in practice.[426] Companies undoubtedly view ethics-involvement as an important brand management tool, because so many innovative pharmaceutical companies are part of industry organizations that set ethical guidelines with rather strict obligations and enforcement mechanisms.[427] However, they evidently prefer these voluntary tools over legal obligations that would interfere with their profit-making.

One starting point for evaluating the "ethics" of the company could be looking at whether they are part of industry organizations and committed to following some ethical guidelines. However, these guidelines are typically more about ethical marketing of pharmaceuticals than public health aspects. What could also work in the favor of the patentee would be if it could show that it has carefully mapped the public health status of the indications of the pharmaceutical in question.[428] It could then be able to show that it has taken some measures or adopted strategies to improve the situation in areas of medical need. If the patentee is taking reasonable steps to

[425] Decreasing legal certainty is a typical effect of incorporation of human rights concerns to legal interpretations. Human rights balancing exercised by the CJEU has evoked much criticism. Walkila 2015b p. 805.
[426] Lee & Hunt 2012 p. 231.
[427] See e.g. list of EFPIA members and EFPIA codes of practice.
[428] This would be called human rights due diligence.

ensure realization of health rights, there would most likely be no need for additional measures in the form of limiting exclusivity.[429]

Thus, it seems likely that the patentee could also affect the likelihood of an injunction being denied. This would be in addition to the public health concerns that are independent of the patentee's conduct. If the situation at hand were a borderline case, the measures taken by the patentee could be the decisive factor. It seems that this kind of pressure might push company strategies into a more human rights friendly direction and indirectly create a form of human rights obligations for pharmaceutical companies. In any case, the patentee would also be equipped to affect the availability of injunctions for itself. With this aspect in mind, it does not seem that the business environment of pharmaceuticals would become too unstable or unpredictable with the described interpretation.

5.5 What Will We Value in the Future?

5.5.1 Values behind Different Injunction Policies

This section will discuss the values related to the different approaches that have arisen in the above analysis. The goal of this section is also to find out what the role of health rights is or should be in patent law. There is no legal dogmatic answer to the question whether health rights should have a bigger role and whether they should be used as an active limitation to pharmaceutical patent enforcement. These questions are inherently about values and answering those means that we as a community must decide how much value we want to give to these interests in relation to one another.

Some form of primacy seems to exist for health rights, but it is quite invisible in routine cases. Yet, even when the interests of the patentee are duly noted, it is held important that patent enforcement does not form a significant barrier to access to medicine.[430] It would seem that at least many human rights scholars would like patent enforcement to be subordinate to health rights whenever reasonable. This reflects valuing human rights above property and trade-related rights.

[429] One aspect that could be monitored is whether the patentee is licensing the invention to others. However, the social value of making a difference between nonexclusive and exclusive producers has been strongly questioned. Licensing should not be an obligation under standard circumstances. See Golden 2010 p. 558.
[430] Owoeye & Owoeye 2018 p. 51.

Another question is when exactly it is reasonable to limit patent enforcement. The *eBay* approach of the USA has been praised for its flexibility and ability to take into account a multitude of different circumstances.[431] Some are happy about the possibility to prevent hold-up, which results in disproportionate rewards for the patentee.[432] Some have promoted a similar approach also in Europe. Yet, discretion inevitably increases legal uncertainty. For this reason some favor a less discretionary approach, which would mean a strong right to exclude.[433] It has also been argued that a strong property rule (right to exclude) should be favored, because it permits patentees to price their unique inventions properly.[434] This can in turn increase efficiency of the market by decreasing the amount of litigation, because settlements are generally favored when parties agree on what the outcome of a court decision would be.[435] On the other hand, some are of the opinion that a court is more competent to set a rough value for a patent than a patentee that possibly abuses their position in a hold-up-like manner.[436] The dilemma here is about how efficiency of the market, fair pricing and competition are interpreted and valued in relation to one another.

Hold-up is generally not an issue in the pharmaceutical sector, because pharmaceutical products typically only consist of a single or a few patented inventions and the patents are owned by the manufacturer.[437] At the time of the eBay decision, pharmaceutical companies were afraid that the decision would hinder them from enforcing their rights. This would have been a problem, because a single pharmaceutical patent can be immensely valuable. Such a phenomenon does not exist e.g. in the software industry, where one product can utilize hundreds of patents.[438] In such a setting it is technically possible that the manufacturer was not aware of all the patents it needed to get a license for. It seems rather ridiculous that a pharmaceutical company that has made the investments necessary to produce a drug would not have checked whether the molecule is patented.[439] Thus, the assumption is that virtually all pharmaceutical patent infringements are

[431] Picht 2016 p. 371.
[432] Merges & Duffy 2011 p. 946–947. Some would also like to use denial of injunctions as a tool to prevent expansion of technology to new parts of life and society, e.g. by making investments to biotechnology less attractive. See Allen 2013 p. 1087.
[433] Picht 2016 p. 371.
[434] Merges & Duffy 2011 p. 948.
[435] Seaman 2016 p. 1980.
[436] Helm 2006 p. 338.
[437] *Id.* p. 339.
[438] Merges & Duffy 2011 p. 954–955.
[439] Helm 2006 p. 339.

willful. This might be relevant when considering injunctions from the perspective of fairness. Punishing the infringer could be held an argument in favor of injunctions. This kind of punitive mindset might lead to a conclusion that injunctions are needed to constrain infringement.

Now it is clear that *eBay* did not actually have a big effect on the enforcement of pharmaceutical patents, because their owners are generally not prone to be involved in hold-up-like situations.[440] Yet, there have been several accusations of opportunistic behavior of innovative pharma in their attempts to keep out generic competition.[441] It has been suggested that these strategies are the reason why pharmaceutical companies have opposed growing discretion of courts in granting injunctions.[442] Another reason is the careful balance of the company's R&D investments and the profits made by a product – this balance being only known to the originator company. It is likely that the license royalties awarded by a court would be less than what the company would get by selling the product exclusively. This would not match the expectations of the company and thus would produce a burden for the business.[443] These perspectives highlight corporate responsibility and punishing the patentee for socially unacceptable conduct. The counter-arguments prioritize protection of legitimate business strategies and viable companies from external concerns. The notion of health rights as an external concern to the patentee intersects with a wider discussion of IP and external effects. The last section will be dedicated to discussing the role of health rights in patent law from this perspective.

5.5.2 Human Rights as External Effects

A trend of the past two decades has been the discussion of external effects in the context of IP.[444] They are costs or benefits that are inflicted on someone else than the decision-maker, in this case consequences to the public from the actions of the patentee. The "public interests" discussed a lot in this thesis can be perceived as such external effects:[445] the patentee's business decisions affect health of patients who might or might not have access to a particular pharmaceutical because of them. Some have noted that the public interest is increasingly identifiable as interests of a particular group – here the patients – so the anonymous protection

[440] Merges & Duffy 2011 p. 954–955.
[441] Helm 2006 p. 340.
[442] *Id.* p. 341.
[443] *Id.* p. 342.
[444] Rahnasto 2003 p. 3; Mylly 2009 p. 30. Most of all they have been discussed in the context of IP and competition law.
[445] Rahnasto 2003 p. 21; Mylly 2009 p. 30.

of public interest might be unnecessary.[446] However, the health of people can have a multitude of effects on the society, from healthcare costs to employment and economy. Therefore it seems simplistic to reduce public health considerations to interests of patients in their own health. Rather, it seems that health is truly a public interest that has effects in all areas of society.

The general consensus seems to be that interests of a patent owner need to be balanced with public interests.[447] This makes IP not an absolute but a rebuttable entitlement.[448] The appropriate balance cannot always be incorporated into patent laws as a general rule, but sometimes it must be struck by competition law or through private negotiations.[449] Traditionally, the "internalization" of public interest concerns into IP laws has been favored instead of employing external tools such as competition law.[450] The approaches identified in this thesis are in essence tools that could be employed to internalize health rights considerations to patent law so that a pharmaceutical patent owner would have to take them into account in their business decisions.

Human rights, including health, currently appear as external to pharmaceutical companies, because they are not directly in the interests of the company. They certainly are external, if they are only employed in extreme court cases to find a balance that would not be supported by conventional patent law. The *eBay* test has internalized public health considerations into US patent law by making the fulfilment of a public interest criterion a prerequisite for injunctive relief. A rise of the proportionality approach and health rights might do the same in the EU with the conditions discussed above. Such internalization could diminish the sense of unfairness that occurs when external tools are brought to constrain "legitimate" patent strategies.

To conclude this chapter, public health is currently an external concern for European pharmaceutical patents. From this perspective it is understandable that some companies and scholars promote "shielding" patents from such concerns. Internalization of public health concerns would create more room for actual interest balancing. Such internalization could be done by adopting a discretionary approach to injunctions so that evaluation of public interests would be part of the infringement trial. From this setting it would then be possible to make

---

[446] Rahnasto 2003 p. 83.
[447] Peukert 2015 p. 132.
[448] Rahnasto 2003 p. 204.
[449] See Rahnasto 2003 p. 205 especially referring to the problem of compatibility. General balancing exceptions are harder to incorporate into patent law than into copyright law.
[450] *Id.* p. 206.

arguments about where the balance should be and in which cases public health would prevail over exclusivity. As long as there is no approved way of bringing health rights arguments to patent enforcement discussions, those interests are more likely to be neglected and any balancing done by courts is bound to be random.

6. Conclusion

The discussion concerning discretion in granting injunctions has often been framed as a debate between those who defend a strong right to exclude and those who wish to abolish it. From this perspective the central question seems to be whether one is pro or contra injunctions – whether they should be issued or not; whether they should maintain their fundamental position in patent law or not. There is also another way to frame the issue. This point of view is not about promoting or opposing the use of injunctions as such. Rather, it is about *how* we should use them.

The fundamental role of injunctions should be utilized to develop patent law and pharmaceutical business to a desired direction. Of course, not even experts are unanimous about what the desired direction is. What this approach highlights is that injunctions should not be treated as a fundamental right but instead as a tool to reach certain aims and promote certain values. If this is what they are for, then they should obviously be discretionary. This notion itself is not a threat to pharmaceutical business or a guarantee to realization of health rights. In practice it only means that it is possible for a court to strike a fair balance in each individual case. The alternative would be that the solution of the legislator is applied blindly to all circumstances. If an extreme situation then arose, the court would have to resort to arguments external to patent law, for example the constitutional law argument that health enjoys primacy over property. This would be likely to lead to surprising decisions, which is usually not in anyone's interest.[451]

Simply allowing discretion to be exercised in the grant of injunctions does not guarantee that a fair balance is found. In this thesis, I have identified factors that should play a part in setting the balance. These include the amount of affected patients and the seriousness of their condition, the relationship of availability and affordability, equivalence of alternatives, actions the patentee

[451] Norrgård 2010 p. 13. It might not even be consistent with the fundamental protection of property, because loss of control over the use of one's property should have a foreseeable basis in the law. See Peukert 2015 p. 143.

has taken to facilitate patient access, reliance of the patentee's business on exclusivity and the effects on the patentee's future R&D investments. There are many ways in which these and other factors can be weighed and balanced against one another in theory and in individual cases. Ultimately the decisions must be made case-by-case, but it would be recommendable that the theoretical balance is set so that it allows for both rights to win under some circumstances.

The main research question in this thesis was whether this kind of discretion to balance different interests exists in European patent law for pharmaceutical patents. Currently hardly any discretion exists in practice. However, the ambiguity of relevant patent law provisions and the increasing importance and direct application of human rights law provide a chance to introduce such discretion. Because of the diversity of European courts dealing with patent matters there are many forums where this kind of discretion could be adopted. The most powerful would be the CJEU that could introduce a binding interpretation of the Enforcement Directive. The UPC could adopt discretion only into its own practice just like national courts. However, all of these would be likely to affect one another despite lack of legal strength.

Discretion, in the meaning of balancing, would in my opinion fit well into European patent law and more broadly European IP law, which is constantly becoming more aware of human rights interests that should be weighed properly – sometimes at the cost of exclusive rights. The notion of property as a fundamental right has limited practical applications, because use of property is perhaps one of the simplest human rights to limit. Allowing public interest arguments an official role in the enforcement of pharmaceutical patents would not necessarily mean undermining pharmaceutical business. Everything depends on where the balance is struck. Interests of the patentee can be highly esteemed even if other interests are recognized as valid. In standard cases the outcomes would most likely remain the same, because there is a lot of respect for property rights. How much emphasis is put on health rights is a question of how much legal uncertainty we are willing to endure in order to ensure that they can be taken into account under appropriate circumstances.

Further research and future developments will show how these perspectives relate to the increasing use of personalized treatments and biosimilars and the blurring of the traditional division to innovators and generic manufacturers. What is also left open here is whether the current forms of protection for pharmaceutical innovation are the most appropriate ones and

what kind of reforms might be made to better reward and incentivize innovation. I also have not addressed the question of what would be the most appropriate way of balancing patent rights and health rights: would it be discretionary injunctions or rather compulsory licenses, competition law or legislative reforms? Additionally, the national systems that must make decisions about balancing resources with patient needs are very relevant for the big picture. The decisions and policies of authorities have huge effects on future prospects in the highly regulated pharmaceutical business. The possibilities and needs for legislative reforms or changes in public policy would be a subject for another study.